

Baxter

I^Tpump

Pain Management System



Operator's Manual

Ipump Pain Management System Operator's Manual

Product Code: 2L3107
2L3107K

Software Versions: 2.03.00

Note: Before operating this pump, the user should carefully read this manual to fully understand how the pump functions and to ensure its safe and proper operation.

Notice

There are risks associated with using anything other than the recommended sets with this device. Sets designated for use with this device are listed in “Accessories, Disposables, and Recommended Sets,” 8-1. Baxter’s warranty on this device will be null and void, and Baxter will assume no responsibility for incidents that may occur if the product is not used in accordance with product labeling.

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Meaning of the CE Mark Symbol



- This symbol represents adherence to Medical Device Directive (MDD) 93/42/EEC.
0123 The electromagnetic compatibility (EMC) requirements are part of the essential requirements of the MDD.

Device: Ipump Pain Management System

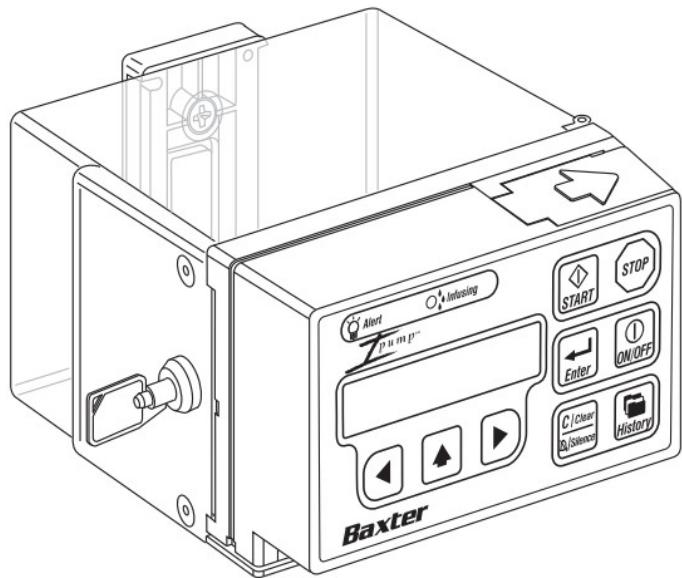
Catalog Number: **REF** 2L3107K

Manufacturer: Manufactured by an affiliate of:
 Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Made in Singapore

Authorized
representative: Baxter S.A.
B-7860 Lessines, Belgium





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Chapter 1. Product Overview

The Ipump Pain Management System (hereafter referred to as the “pump”) is indicated for the controlled delivery (continuous, intermittent, and continuous plus intermittent) of analgesic, sedative, and anesthetic solutions through clinically acceptable routes of administration including intravenous, subcutaneous, and epidural, and for regional (local) analgesia applications.

This lightweight, compact pump can be battery operated for portability or connected to an AC power source for stationary use. A specially designed optional locking pole-mounting clamp allows the pump to be attached to a standard IV pole. With the pole clamp removed, the pump can be placed into a comfortable carrying case.

Key Features

The pump’s key features include:

- Air sensor
- Preventive maintenance alert
- Multilanguage interface
- Detailed history display and printout capability
- Ability to transfer configuration data via a serial port to another pump
- Upstream and downstream occlusion detectors
- Programmable limits for Patient Controlled Analgesia (PCA) doses

Programming Options

The pump can be programmed to provide:

- PCA, Basal and PCA (Basal+PCA), or Continuous infusions
- Infusion rates in mL, mg, and μ g
- Physician-prescribed values for the desired therapy
- Clinician- or institution-selected operating limits

When the pump is programmed for PCA, the patient has the option of self-administering analgesic medications on an as-needed basis. The Basal+PCA programming option combines this patient-controlled method with a minimum continuous dose.

Record Management

The pump tracks the programming, time, and history of each infusion. All of this data is retained in the memory of the pump's microprocessor when the pump is off.

The pump is equipped with a real-time clock that provides the correct date and time for record management. The date and time are displayed on the screen and included on any printouts generated by using the optional printer.

Security

For patient security, the pump may be configured to require the:

- Insertion of a key in the cover lock (KEY ONLY)
- Entry of a security code before programming or changing the prescription (CODE ONLY)
- Both key insertion and code entry (KEY+CODE) – the factory default configuration

Note: If the pump is configured to require only the entry of a security code, the cover that holds the IV bag is optional.

Note: Use of security features, such as KEY+CODE, should be governed by individual care site policies and regulations regarding the use of controlled substances.

Organization of This Manual

This manual is designed for use by trained health care professionals.

! WARNING ! This manual is intended for clinicians only. Do not permit patients to have access to this manual.
Do not disclose the pump's security codes to patients.

The chapters of this manual provide the following information:

- Chapter 2 – Ipump Pain Management System Description – covers what is included in the shipping package and the components of the pump.
- Chapter 3 – Setting Up the Pump – describes how to install the pump battery, load and prepare the tubing set, mount the pump on a pole, set up connections, and remove the cover.
- Chapter 4 – Configurable Options – lists the factory-set options and how to reset these values.
- Chapter 5 – Using the Pump – contains step-by-step instructions for setting up prescriptions, starting and stopping infusions, and accessing and reviewing a patient’s prescription history.
- Chapter 6 – Alerts and Alarms – provides an alphanumeric list of the alert and alarm messages that may occur and how to resolve them.
- Chapter 7 – Preventive Maintenance – contains references on conducting functional checks and storage procedures and authorized service center contacts.
- Chapter 8 – Accessories, Disposables, and Recommended Sets – contains a list of accessories, including bags and sets, that can be used with the pump.
- Chapter 9 – Technical Specifications – contains a list of the pump’s physical and operational specifications.
- Chapter 10 – Electromagnetic Compatibility Statement – identifies the EMC standards to which the pump was subjected, the test levels and levels met, and general EMC guidance.
- A Glossary and an Index are included to assist in using the pump and this manual.

Safety Summary

General Information

Although the pump has been designed and manufactured to exacting specifications, it is not intended to replace trained personnel in the supervision of pain management infusions.

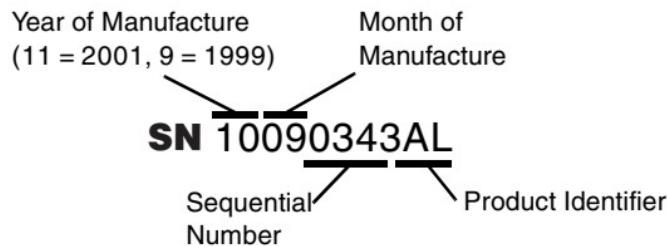
This product is classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only in accordance with UL 2601-1 (UL 60601-1), Second edition, and CAN/CSA C22.2 No. 601.1. In accordance with these documents, and in accordance with international standard IEC 60601-1 (1988-12) Medical Electrical Equipment — Part 1: General Requirements for Safety, the pump is classified as:

- Class II, internally powered
- Type CF
- Drip-proof (IPX1)
- Not suitable for use with flammable anesthetic mixtures with air, oxygen, or nitrous oxide
- Continuous operation

Before operating this pump, the user should carefully read this manual to understand fully how the pump functions and to ensure its safe and proper operation. This manual has been developed with consideration of the requirements in the Collateral Standard IEC 60601-2-24, First Edition 1998-02, Medical Electrical Equipment, Part 2-24: Particular Requirements for the Safety of Infusion Pumps and Controllers.

When disposing of this device or the sets designed for use with the device, follow local regulations and guidelines.

Serial Number Format



Label Symbol Definitions

| Label | Description |
|---|--|
| IPX1 | Drip-proof equipment: enclosed equipment protected against dripping fluids. |
|  | Connection port for the AC to DC converter/adapter. |
|  | This product is classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only in accordance with UL 2601-1 (UL 60601-1), Second edition, and CAN/CSA C22.2 No. 601.1. |
|  | <p>The symbol of conformity to the Council directive 93/42/EEC. EU Authorized Representative: Baxter S.A. B-7860 Lessines, Belgium</p> |
|  | CAUTION, Consult Accompanying Documents (Read the operator's manual for complete instructions before using this device.) |
|  | Type CF applied part. * |

* The "Type CF Applied Part" symbol indicates the level of electric shock protection for the patient-contacting parts such as the PCA button and the IV set. UL/EN 60601-1 defines Type CF as providing greater protection than Type B or Type BF.

| | |
|---|---|
|  | <p>Electrostatic Sensitive Devices</p> <p>(The pins of the PRINTER/COMM connector are subject to Electrostatic Discharge and should not be touched. Refer to page 10-7 for additional information.)</p> |
|  | <p>Symbol (WEEE 2002/96/EC) Crossed-out wheeled bin</p> <p>For product disposal, ensure the following:</p> <ul style="list-style-type: none"> • Do not dispose of this product as unsorted municipal waste. • Collect this product separately. • Use collection and return systems available to you. <p>Bar below bin</p> <ul style="list-style-type: none"> • Product distributed after August 13, 2005. <p>For more information on return, recovery, or recycling of this product, please contact your local Baxter representative.</p> |
|  | Manufacturer |
|  | Authorized Representative in the European Community |
| REF | Catalog Number |
| SN | Serial Number |

Definitions

The safety and information labels included in this manual are defined as follows:

- **Warning** messages indicate a possible hazard that, if not avoided, could result in severe personal injury or death.
- **Caution** messages indicate a problem or unsafe practice that, if not avoided, could result in minor or moderate personal injury or product or property damage.
- **Note** messages provide information that supplements the accompanying text.

Warnings

- ! WARNING !** This manual is intended for clinicians only. Do not permit patients to have access to this manual. Do not disclose the pump's security codes to patients.
- ! WARNING !** The pump has been configured with factory defaults. Please verify the appropriateness of the pump configuration for your institution prior to initial use. See "Configurable Options," 4-1, for more details.
- ! WARNING !** Baxter will assume no responsibility for incidents that may occur if the product is not used in accordance with product labeling.
- ! WARNING !** Always read and follow the instructions which accompany the source container and the administration sets you are using. Carefully follow any label copy instructions for loading, removing, and reloading the set, as well as the recommended set change interval. For optimal pump performance, set use should not exceed the change interval shown on the set's label copy or 72 hours, whichever is less.

- ! WARNING !** For infection control purposes, consider the set change interval recommended by the United States Centers for Disease Control and Prevention (CDC), your institution's guidelines, and the instructions provided with the administration set, using whichever is most appropriate.
- ! WARNING !** Only use sets manufactured by Baxter as specified in "Accessories, Disposables, and Recommended Sets," 8-1.
- ! WARNING !** To reduce the risk of stored fluid being infused after a downstream occlusion occurs, relieve the pressure by disconnecting the system above the occlusion before freeing the occlusion.
- ! WARNING !** The tubing set MUST NOT be connected to the patient while priming.
- ! WARNING !** When the Upstream Occlusion Detection feature is enabled, and the automatic upstream occlusion test is performed, the pump may withdraw up to 0.03 mL of fluid and subsequently deliver up to 0.09 mL of fluid at the end of the test period. If these volumes are clinically significant for the patient, please take appropriate measures. See "Upstream Occlusion Testing," 5-18, for more details.
- ! WARNING !** When infusing at low flow rates (less than 0.5 mL/hr), the pump may not detect air in the tubing. In addition, when infusing at low flow rates (less than 0.5 mL/hr), and there is an upstream occlusion, it is possible for the pumping mechanism to pull air through the tubing wall and into the fluid path of the set. For infusion routes where air in tubing may be clinically significant for the patient, Baxter strongly recommends the use of administration sets containing an air eliminating filter. See "Accessories, Disposables, and Recommended Sets," 8-1, for a list of air eliminating administration sets available for this pump.
- ! WARNING !** Clamp tubing distal to the pump before opening the tubing door or troubleshooting any pump connected to a patient.

! WARNING ! Do not use in the presence of flammable anesthetics.

! WARNING ! Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.

- Epidural administration of anesthetics is limited to short-term infusion (not to exceed 96 hours) with indwelling catheters specifically indicated for short-term anesthetic epidural drug delivery.
- Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for analgesic epidural delivery.
- To prevent the infusion of drugs not indicated for epidural use, do not use IV administration sets incorporating injection sites during epidural delivery.
- It is strongly recommended that the pumps programmed for epidural drug delivery be clearly differentiated from those programmed for other routes of administration.

! WARNING ! Hospital protocol for the management of high alert medications must be followed with this device.

! WARNING ! To help prevent medication errors, Baxter recommends that both the clinician programming the pump and another clinician check the accuracy of prescription and programming information before the infusion is started.

! WARNING ! Hospital and nursing protocols for the prescription and delivery of narcotic analgesic drugs, including the education, monitoring, and care of patients receiving such drugs, must be followed when dispensing narcotic analgesic drugs to patients using this device.

! WARNING !

Patients receiving narcotic analgesic drugs with any patient-controlled analgesia (PCA) pump should be instructed in the proper use of the device. Instructions should include that only the patient or a licensed healthcare practitioner may operate the PCA button, unless the prescribing physician authorizes a lay caregiver to do so. Without physician authorization, operation of the device by all other persons is prohibited.

! WARNING !

When using this pump, periodic patient monitoring must be performed to ensure that the infusion is proceeding as expected. The pump is capable of developing positive fluid pressures to overcome widely varying resistances to flow such as resistance imposed by small-gauge catheters, filters, or intra-arterial infusion. The pump is designed to stop fluid flow when an alarm occurs, but it is neither designed nor intended to detect infiltrations and will not alarm under infiltration conditions.

! WARNING !

This pump should be used only with the Baxter accessories specified for it. There are risks associated with using anything other than the recommended accessories with this pump. Accessories designated for use with this pump are listed in "Accessories, Disposables, and Recommended Sets," 8-1.

! WARNING !

The pump has not been tested for use in the vicinity of magnetic resonance imaging (MRI) equipment or ESU equipment. The pump may malfunction and cease to operate.

! WARNING !

To avoid personal injury, ensure that the IV pole is stable and secure. Ensure that the pole can support the pump, along with any other devices, without tipping or falling. The pole diameter should be between 1.3 and 3.2 cm (0.5 and 1.25 inches).

Cautions

- CAUTION** In the US, use of this pump is restricted to sale or use by, on the order of, or under the supervision of a qualified physician.
- CAUTION** There are no internal user serviceable parts or adjustments.
- CAUTION** When using the optional AC adapter, use earth-grounded AC outlets only. When grounding reliability is in doubt, the equipment should be powered by its battery.
- CAUTION** Variations in epidural catheter sizes can cause downstream occlusion alarms. If an occlusion alarm occurs with no visible occlusion, change to a larger diameter and/or shorter catheter. If occlusion alarms continue, contact your nearest authorized service center.
- CAUTION** Do not use sharp objects to press keys.
- CAUTION** The time to detect occlusions increases proportionally with a decrease in flow rates. At flow rates below 0.5 mL/hr, an occlusion may not be detected. Baxter recommends that extra care be taken to ensure that neither the tubing nor the bag are pinched, twisted, or occluded.
- CAUTION** The pump can be configured with the upstream occlusion detection disabled. If this feature is disabled, Baxter recommends that extra care be taken to ensure that neither the tubing nor the bag are pinched, twisted, or occluded.
- CAUTION** This pump has configurable options. Operating modes and input parameter selections may vary as a function of the selected configuration.

CAUTION

As with all medical electronic equipment, exercise care to avoid exposing this pump to powerful sources of electromagnetic interference. This device design has been tested to current U.S. and European standards and guidelines for medical devices. The pump was not found to be affected adversely by these susceptibility tests and will perform safely. The pump's emissions also were found to be acceptable. Using the pump near operating equipment that radiate high-energy radio frequencies (such as electrosurgical/cauterizing equipment, two-way radios, or cellular telephones) may cause false alarm conditions. If this happens, reposition the pump away from the source of interference or turn off the pump.

CAUTION

Use only accessory equipment complying with the pump's safety requirements; failure to do so may lead to reduced safety levels of the resulting system. Consideration relating to accessory choice shall also include the use of the accessory in the patient vicinity, and evidence that the safety certification of the accessory has been performed in accordance with the appropriate UL2601-1 (UL 60601-1) or IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

CAUTION

Use this product for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer. If interconnection with other infusion systems and/or parallel infusion is desired, make sure a recommended Anti-Reflux Y-Site Extension Set (2L3506) or a set containing an integral Y-Site (2L3525, 2L3526, or 2L3527) is used to prevent back flow.

CAUTION

Follow the cleaning schedule and methods defined in "Preventive Maintenance," 7-1, to ensure the proper maintenance of the pump.

CAUTION

Any equipment connected to the pump through the PRINTER/COMM port must conform to the electrical safety requirements of IEC 60601-1.

CAUTION

When attaching the pump to an IV pole, ensure that it has been clamped securely.

CAUTION

If the pump is attached to an IV pole, ensure that the device is mounted where the main body is easily accessible and the IV administration set can be installed in the loading mechanism without stretching or kinking the tubing.

Notes

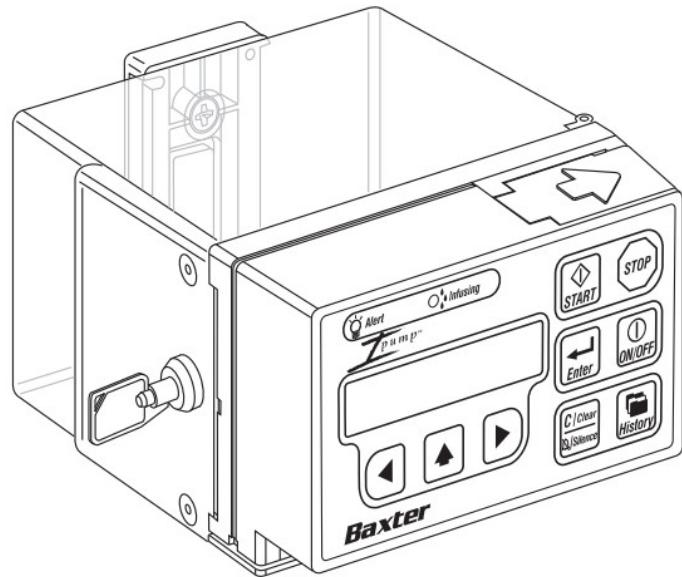
Note: In the US, grounding reliability can be achieved only when this equipment is connected to an earth-grounded receptacle marked "Hospital Grade." When grounding reliability is in doubt, the equipment should be battery powered.

Note: The pump may be configured to the specific needs of the operator or institution. See the *Ipump Pain Management System Global Configuration Manual* for further information.

Note: Baxter requests that parties acquiring this device:

- Promptly report receipt of this device to Baxter.
- Report the device's purchase, receipt in trade, return after sale, loss, destruction, or retirement.
- If this is an initial purchase from Baxter, returning a signed copy of the packing list to Baxter will fulfill this request. Contact your local Baxter service facility for additional information.

Note: No natural latex was used in the manufacture of this pump.



Chapter 2. Ipump Pain Management System Description

This section will acquaint you with the various components of the pump, including the:

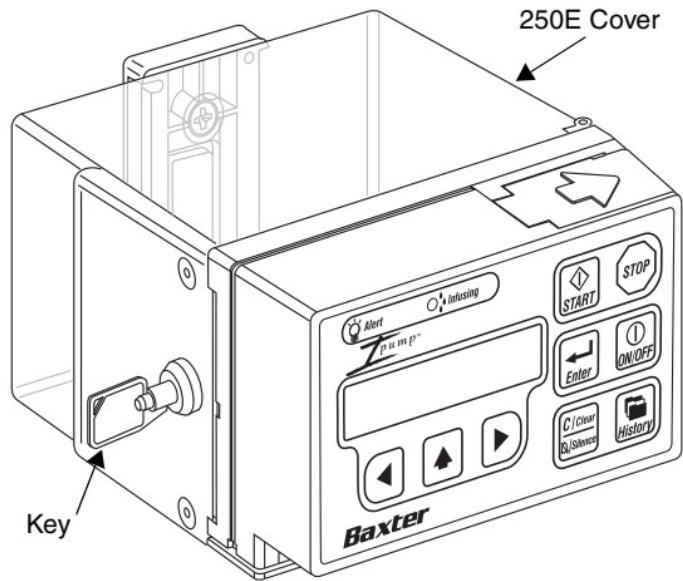
- Ipump Pain Management System Package Contents
- Pump Components
- Pump Key Pad
- Action Keys
- Pump Symbols
- LCD Symbols

Ipump Pain Management System Package Contents

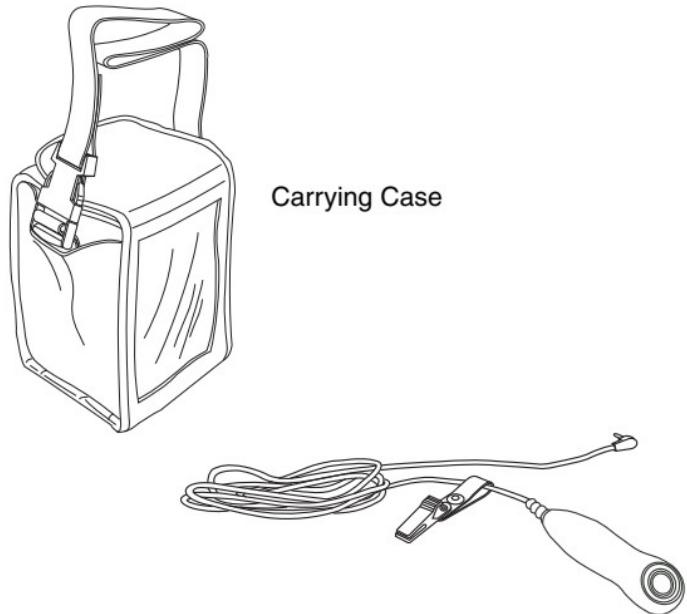
When the pump arrives, check to make sure that you have all the required parts, which should include the:

- Ipump Pain Management System
- 250E Cover
- Key(s)
- PCA Cord and Button
- Pump Carrying Case
- Operator's Manual(s)
- Configuration Manual

If you need to connect the pump to an electrical power source, you will also need a Baxter AC adapter, which is sold separately. (See "Accessories, Disposables, and Recommended Sets," 8-1.)



Ipump Pain Management System



PCA Cord and Button

Figure 2-1 Ipump Pain Management System Package

Pump Components

The pump is a linear peristaltic pump that consists of a:

- Key pad for programming
- Container (cover) that holds the fluid bag in place and can be locked
- Tubing door that holds the tubing in place and protects it
- Battery compartment to hold the battery
- AC Power port
- Printer port
- PCA port

Pump Key Pad

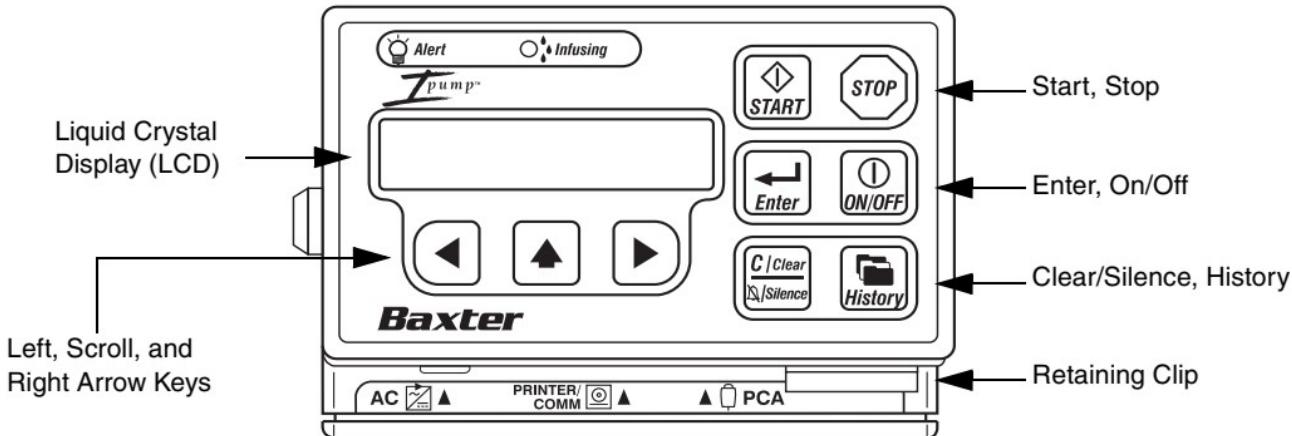


Figure 2-2 Pump Key Pad

Note: When operating on battery power only, after a period of inactivity the back light and key pad are deactivated to save energy. Press any key other than the **START** key once to reactivate the back light and key pad, then press the desired action key(s).

Action Keys

Table 2-1 Action Keys

| Action Key | Description |
|---|---|
|  | The ON/OFF key powers up and powers down the pump. Press this key once to power on the pump. Press this key twice to power off the pump. For more detailed information, see “Turn On the Pump,” 5-5, and “Turn Off the Pump,” 5-6. |
|  | The left (⇐) and right (⇒) arrow keys move the cursor (↑) on the LCD to the left and right. |
|  | The scroll (↑) key displays the next available option or scrolls through the digits 0-9 at the cursor’s (↑) current position on the LCD. Press and hold the key to increase the scrolling speed. |
|  | The Enter key sets the value displayed on the LCD. |

Table 2-1 Action Keys — continued

| Action Key | Description |
|---|--|
|  | <p>The START key begins the operation of the pump and can also be configured to act as a PCA button. If all of the required programming values have been entered, the START key initiates the infusion.</p> <p>Following the resolution of certain alerts or alarms, pressing the START key resumes the infusion if the condition no longer exists.</p> |
|  | <p>The STOP key must be pressed twice in 1 second to stop the operation of the pump. After you press the STOP key, you can press the ON/OFF key to turn the pump off.</p> |
|  | <p>The History key displays the infusion history on the LCD.</p> |
|  | <p>The Clear/Silence key either clears the data shown on the LCD or silences an alert or alarm signal generated by the pump.</p> |

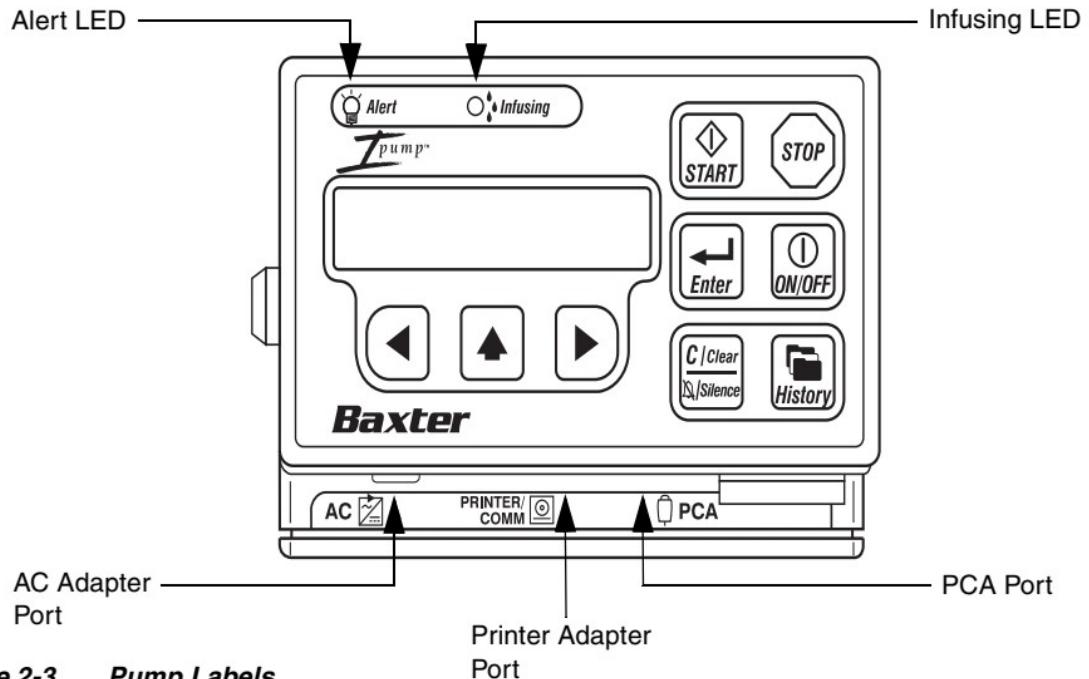


Figure 2-3 Pump Labels

Pump Symbols

Table 2-2 Pump Symbols

| Symbol | Description |
|--|---|
|  | The Alert Light Emitting Diode (LED) flashes red if it is activated by an alert or an alarm. |
|  | The green Infusing LED flashes intermittently when the pump is operating normally. |
| PRINTER/ COMM  | The printer/communication port is an RS232-compatible port (connection) for a printer adapter. |
| AC  | The AC adapter port is used to plug in a Baxter AC adapter approved for use with the pump. |
|  PCA | The PCA port is used to connect the PCA cord, which is attached to the PCA button. |

LCD Symbols

| Symbol | Description |
|---|--|
|  | When the 9-volt battery appears on the screen, it is the primary power source. |
|  | If an electrical plug is displayed, the pump is powered by an AC adapter. |

Chapter 3. Setting Up the Pump

The steps required to set up and use the pump include:

- Installing and changing the battery
- Connecting the AC adapter
- Connecting the PCA cord
- Unlocking and opening the cover
- Removing or changing the cover
- Preparing, loading, and changing the tubing set and fluid bag
- Attaching or removing the pump from a pole (optional)

The following sections contain step-by-step procedures for completing these tasks.

Installing and Changing the Battery

When you use the pump, you must install a 9-volt alkaline battery to:

- enable patients to carry the portable pump, and
- ensure that the pump continues to operate during a power outage.

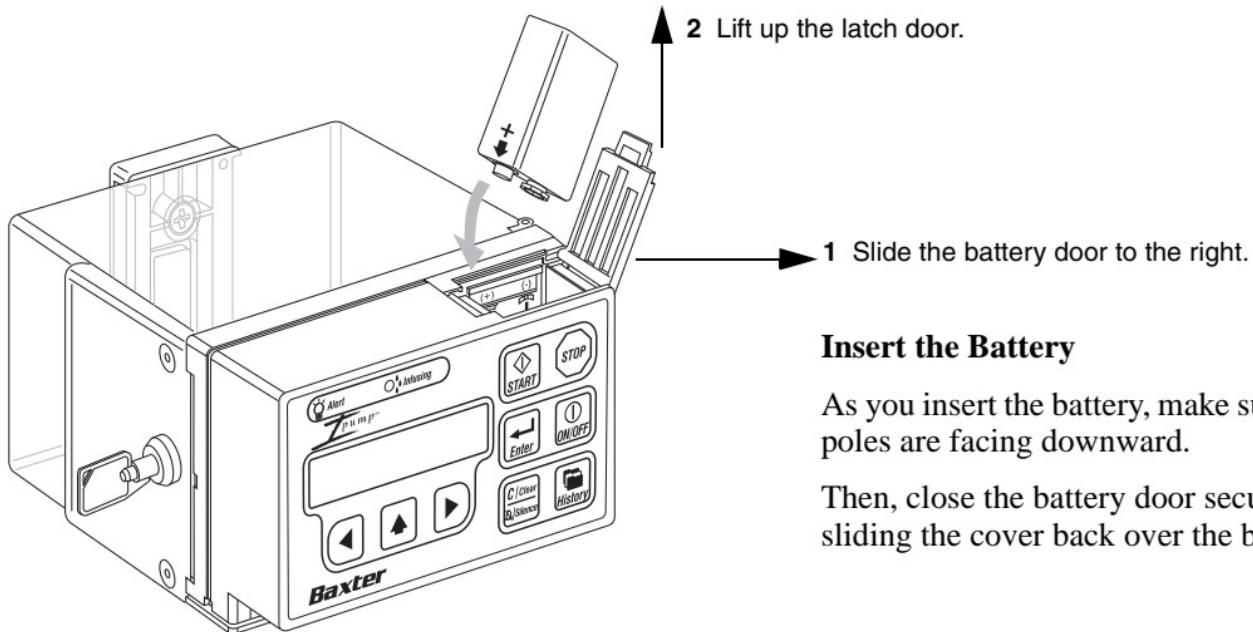
This section covers how to install the battery and how to replace it when necessary.

Note: If all power sources have been disconnected or are not functioning, the pump will emit a chirping sound and the red LED will flash for a short period of time to notify the user that no power source is available. To silence the chirp, press the **Clear/Silence** key.

Install the 9-volt Alkaline Battery

CAUTION **Do not use zinc-air, ni-cad, or any other rechargeable batteries with the Ipump Pain Management System.**

1. Open the battery compartment by sliding the battery latch door on the top of the pump in the direction of the arrow (see Figure 3-1) and then lifting the latch door.
2. Check the (+) and (-) labels inside the battery compartment to determine the correct placement of the battery.
3. Insert the battery with the poles down into compartment, close the battery door, and slide it back to the original position.



Insert the Battery

As you insert the battery, make sure that the poles are facing downward.

Then, close the battery door securely by sliding the cover back over the battery.

Figure 3-1 Inserting the Battery

Change the Battery

The 9-volt alkaline battery should be changed regularly. If battery voltage drops below the required level:

- A LOW BATTERY alert will appear on the pump's screen,
- The red **Alert** and green **Infusing** LEDs will flash, and
- An audible alert will sound.

You must do one of the following before changing the battery as described in “Install the 9-volt Alkaline Battery,” 3-2:

- If the pump is powered by the AC adapter, you can replace the battery at any time without interrupting operation. During the battery change, the pump will display the FCH message and the BATTERY MISSING alert, but will not interrupt service.
- If the pump is battery-operated and the infusion has not been started, press **Enter** to acknowledge the alert and replace the battery (the pump turns off during the battery change). Then, turn the pump on and re-enter the prescription after the power-on self test as described in “Using the Pump,” 5-1.

- If the pump is battery-operated and the infusion has been started, stop the pump by pressing **STOP** twice in one second and replace the battery (the pump turns off during the battery change). Then, turn the pump on. The pump will retain the prescription and therapy history.

To resume the infusion, press **START** at the PUMP READY PRESS START or PUMP READY START OR CLEAR screen after the power-on self test runs. The infusion will resume after the memory test and upstream occlusion test (if the pump is configured for upstream occlusion detection) are complete.

If the pump is configured as CODE ONLY, the SELECT ACTION options may be accessed prior to resuming the infusion; press **Clear/Silence** at the PUMP READY START OR CLEAR screen after the power-on self test runs. See “Restarting the Infusion,” 5-33, for more information.

Note: Always follow manufacturer's recommendations and applicable local regulations when using or disposing of batteries.

Connecting the AC Adapter

The AC adapter must be used to plug the pump into an AC electrical power source. The 9-volt alkaline battery must be inserted in the battery compartment as a backup power source in the event of AC power interruption and to allow patient ambulation.

To use the AC Adapter:

1. Make sure the 9-volt alkaline battery is inserted in the battery compartment. See "Insert the Battery," 3-3.
2. Plug the AC adapter into an AC outlet before connecting it to the pump. (This helps prevent an alarm condition that may occur when the pump's battery is low and the AC adapter is plugged into the pump before it is plugged into the AC outlet.)

Note: If the alarm condition occurs, turn the pump OFF and then ON again and reprogram the infusion.

3. Align the red dot on the connector with the red dot on the AC connector port (see Figure 3-2). If these dots are not lined up, the connector will not seat firmly in the port.
4. Insert the AC adapter cable connector into the pump's AC port.
5. To disconnect the AC adapter from the pump, pull back on the connector ring to release the locking mechanism, then disconnect the connector.

Align red dots on AC Adapter and Connector Port

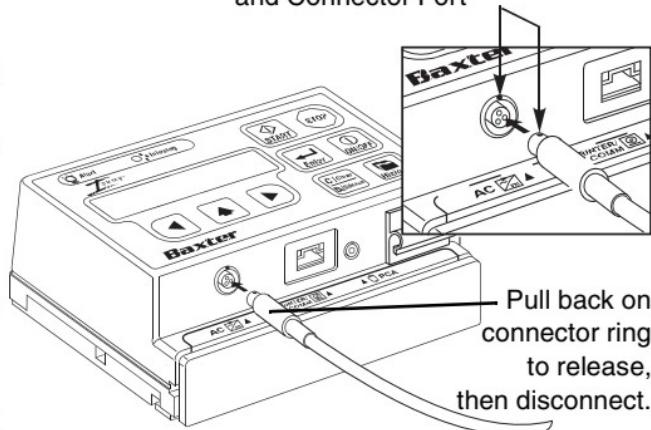


Figure 3-2 AC Adapter Connection

CAUTION

The locking mechanism **must** be released before disconnecting the AC adapter connector. Failure to do so will result in damage to the connector.

Connecting the PCA Cord

The PCA button is attached to the PCA cord. The pump can be configured to start a PCA infusion by using:

- Only the PCA button, or
- Either the PCA button or the **START** key.

If the pump is configured for use only with the PCA button, failure to connect the PCA cord after programming for the PCA or Basal+PCA mode will generate the alert message **PCA BUTTON NOT CONNECTED** when the infusion is started.

The PCA button is **not required** if the pump is programmed to operate in Continuous mode.

The PCA button is **required** if the pump is programmed to operate in the PCA or Basal+PCA mode with a non-zero PCA dose.

The PCA button is **not required** if the pump is programmed to operate with a 0.0 mL PCA dose in the Basal+PCA mode.

! WARNING ! Patients receiving narcotic analgesic drugs with any patient-controlled analgesia (PCA) pump should be instructed in the proper use of the device. Instructions should include that only the patient or a licensed healthcare practitioner may operate the PCA button, unless the prescribing physician authorizes a lay caregiver to do so. Without physician authorization, operation of the device by all other persons is prohibited.

To connect the PCA button:

1. Plug the PCA cord into the PCA connector on the pump and gently press the cable into the retaining clip.

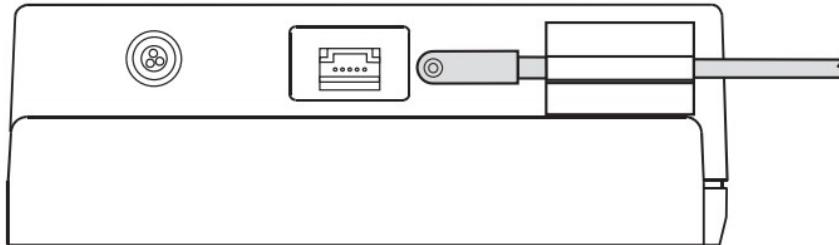


Figure 3-3 PCA Cord Connection Through the Retaining Clip

2. Make sure the PCA cord and plug are installed as shown in Figure 3-4.

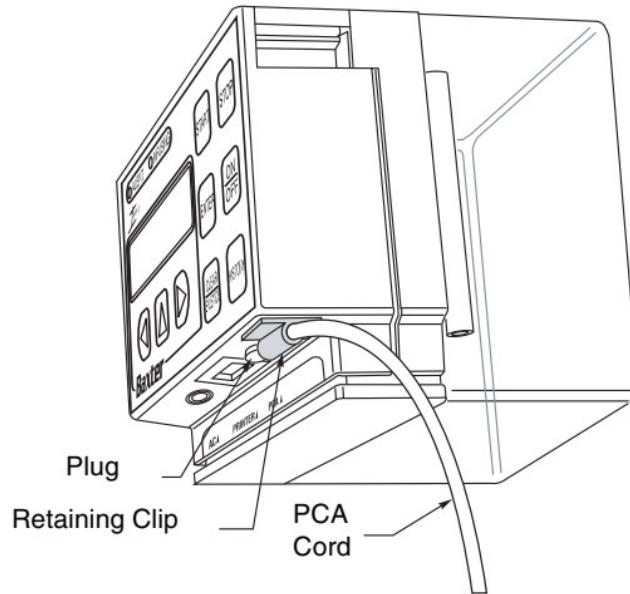


Figure 3-4 Connected PCA Cord and Plug

Unlocking and Opening the Cover

1. If the pump is attached to a pole, remove it as described in “Remove the Pump from the Pole,” 3-23.
2. Place the pump face down.
3. If the cover is locked, insert and push in the key, then rotate it one-quarter turn counterclockwise. Then, open the cover. The key will remain in the lock whenever the cover is unlocked. To lock the cover, insert and push in the key, then rotate it one-quarter turn clockwise (see Figure 3-5).

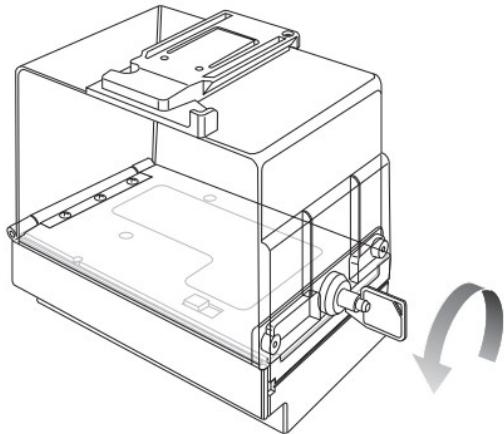
Removing or Changing the Cover

The highest level of drug security is attained by programming the combination of KEY+CODE and using the cover. However, if the pump is configured for CODE ONLY, the cover may be removed completely.

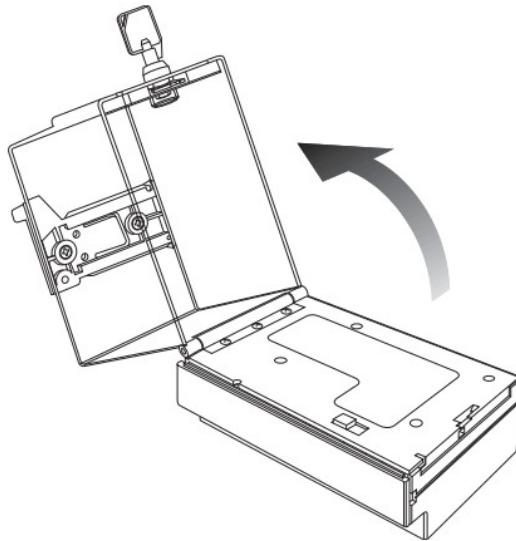
1. To remove or change the cover, unlock the cover (if necessary) and open it as described above.
2. Place the pump face down.
3. Detach the cover (and hinge cover, if removing the 250E bag cover) from the pump by removing the three screws on the hinge assembly (see Figure 3-6). Store the cover and hinge cover for future use.

Note: The hinge cover is for use with 250E bag covers only.

4. Attach the new cover, if desired, by aligning the hinge assembly and replacing the three screws.



Unlock the cover.



Open the cover with the
pump face down.

Figure 3-5 Unlocking and Opening the Pump Cover

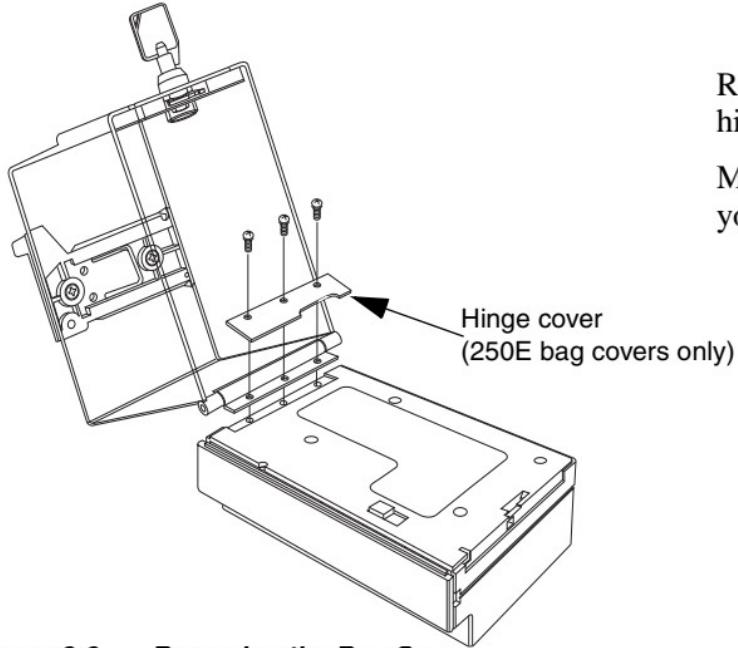


Figure 3-6 Removing the Bag Cover

Remove the three screws that secure the hinges.

Make sure that you line up the hinges when you reattach the fluid bag cover.

Preparing, Loading, and Changing the Tubing Set and Fluid Bag

During the preparation of the fluid bag and tubing set, you must use aseptic technique, follow hospital guidelines for changing bag sets, and follow the directions for the fluid bag provided by the manufacturer. The pump may be used with several types of fluid bags, including:

- Baxter 100 mL or 250 mL bags, or
- Viaflex or IntraVia containers, or similar fluid bags up to 500 mL

! WARNING ! This pump should be used only with the Baxter accessories specified for it. There are risks associated with using anything other than the recommended accessories with this pump. Accessories designated for use with this pump are listed in “Accessories, Disposables, and Recommended Sets,” 8-1.

The following directions are provided to assist you in using the different types of bags in the pump. These directions cover:

- Loading the Tubing Set
- Filling and Loading the Fluid Bag
- Changing the Tubing Set and/or Fluid Bag

Loading the Tubing Set

1. Unlock and open the cover as described in “Unlocking and Opening the Cover,” 3-10.
2. Release the tubing door by sliding the silver latch toward the side of the pump as indicated by the arrow.
3. Open the tubing door by pulling it down.
4. Load the tubing set into the groove in the tubing door. Ensure the sensor tab (see **INSET**) is properly positioned.

! WARNING ! Only use sets manufactured by Baxter as specified in “Accessories, Disposables, and Recommended Sets,” 8-1.

! WARNING ! Avoid getting any liquids on the tubing set, inside the tubing door, or in the tubing channel. Air sensor functioning could be compromised or permanent damage may result.

CAUTION Ensure that the set is oriented as shown in Figure 3-7 and Figure 3-8. The pump will not work if the sensor tab is missing or misaligned.

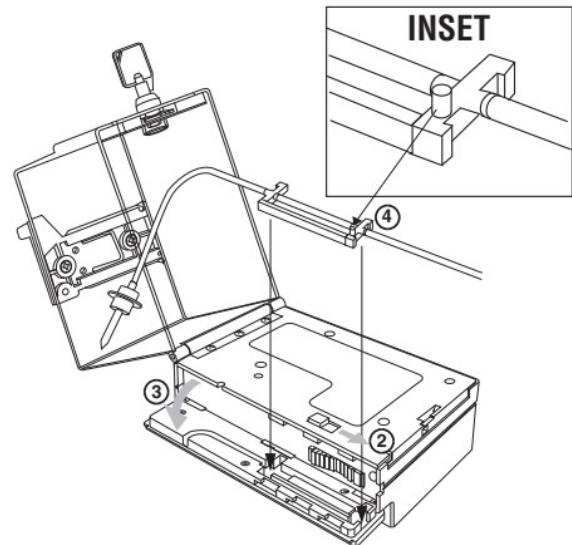


Figure 3-7 Load Tubing Set

5. Ensure that the set's longer tubing segment exits the side of the pump. The shorter segment must follow the curved groove, exiting behind the pump for attachment to the bag (see Figure 3-8).

CAUTION

When closing the bag cover, ensure that neither the tubing nor the bag are pinched, twisted, or occluded. Run your fingers around the edges of the bag cover to ensure that no part of the bag or tubing is pinched in the cover. Do not force the bag cover closed if it appears to be obstructed. Clear any obstruction and then close the bag cover.

6. Close and latch the tubing door as follows. Slide the silver latch toward the side of the pump as indicated by the arrow, close the tubing door, and release the latch so that it returns to its original position.

To avoid pinching the tubing, do not let the tubing fall out of the groove when you are closing the tubing door. Failure to latch the tubing door will prevent the cover from closing.

! WARNING ! **Failure to latch the tubing door properly and completely may result in a no flow condition.**

! WARNING ! **If the tubing is pinched by the closed tubing door, resistance to flow may increase and fluid delivery to the patient may be compromised. If this occurs, open the bag cover, reseat the tubing and check the tubing door for proper closure, close the bag cover, then restart the pump.**

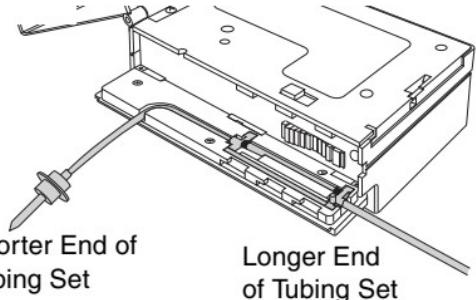


Figure 3-8 Tubing Set Correctly Positioned

Note: Whenever the pump is stopped, it automatically closes off the tubing to reduce the risk of a free flow condition. When the tubing is removed from the pump, the anti-siphon valve on the set reduces the risk of a free flow condition when used in accordance with the set's instructions.

Filling and Loading the Fluid Bag

CAUTION All luer-lock connections must be properly tightened. Over tightening may crack the luer and cause leakage.

CAUTION Follow any directions provided by the manufacturer of the fluid bag being used.

1. Open the package and carefully remove the bag.
2. For Baxter empty luer-lock 100 mL or 250 mL bags:

Note: Do not confuse the nonvented cap (which is supplied in its own package) with the cap attached to the outlet tubing. The cap attached to the outlet tubing is not airtight and will not prevent fluid leakage.

- Fill a sterile syringe with the solution to be placed in the bag.
- Remove and discard the cap from the outlet tubing of the bag.
- Connect the syringe to the female luer-lock fitting on the bag's outlet tubing. (Do not use a needle.)

- Inject the solution into the bag. If necessary, refill the syringe and repeat the process. (The bag will hold approximately 100 mL or 250 mL, depending on the bag selected.)
- Remove all air from the bag by aspirating with the syringe, and then remove the syringe.
- If the bag is being used immediately, do not use the nonvented cap. Connect the luer-lock fittings between the bag and the pump tubing set. (The bag must be connected to the shorter segment of the tubing set.)
If the bag is being stored for later use, connect the nonvented cap to the bag after the bag is filled.

For Baxter Viaflex, IntraVia, or similar spike fluid bags:

- Add any additional drug/diluent to the bag using a syringe and needle appropriate for the injection port of the bag. Mix or shake the bag to dilute the drug and solution appropriately.
- Remove all air from the bag by aspirating with the syringe, and then remove the syringe.
- Insert the tubing set spike into the outlet port of the bag. Ensure that the spike is inserted up to the ridge on the spike.

! WARNING ! To help prevent injuries, always follow your facility's policies and procedures when using and disposing of needles.

3. Remove the air from the remainder of the tubing set by following the procedure in “Prime the Tubing Set,” 5-16.

! WARNING ! The tubing set MUST NOT be connected to the patient while priming.

4. Connect the distal end (longer segment) of the pump tubing set to the patient's access site, making certain that the luer-lock connection is properly tightened.

Note: To prevent upstream occlusions, open any optional clamp on the bag upstream of the pump before starting the infusion.

5. After connecting the bag to the pump tubing set, place the tubing in the groove in the tubing door (see "Loading the Tubing Set," 3-14) then close the tubing door.
6. Verify that the tubing door is properly closed and latched.

! WARNING ! Failure to latch the tubing door properly may result in a no flow condition.

7. **For Spiked Bag & Set Loading:** Take the spiked bag and fold it about 1/3 of the way from the spike port. Place the bag in the cover with the set pulling across the hinge of the pump and the spike pointing towards the lock or upper corner above the lock (see Figure 3-9).
For Luer Lock Bag and Set Loading: Place the Luer Lock bag in the cover with the Luer Lock connector closest to the pump (see Figure 3-9).
8. Pull the pump body over the bag cover making sure the set is not pinched in the cover in any way.

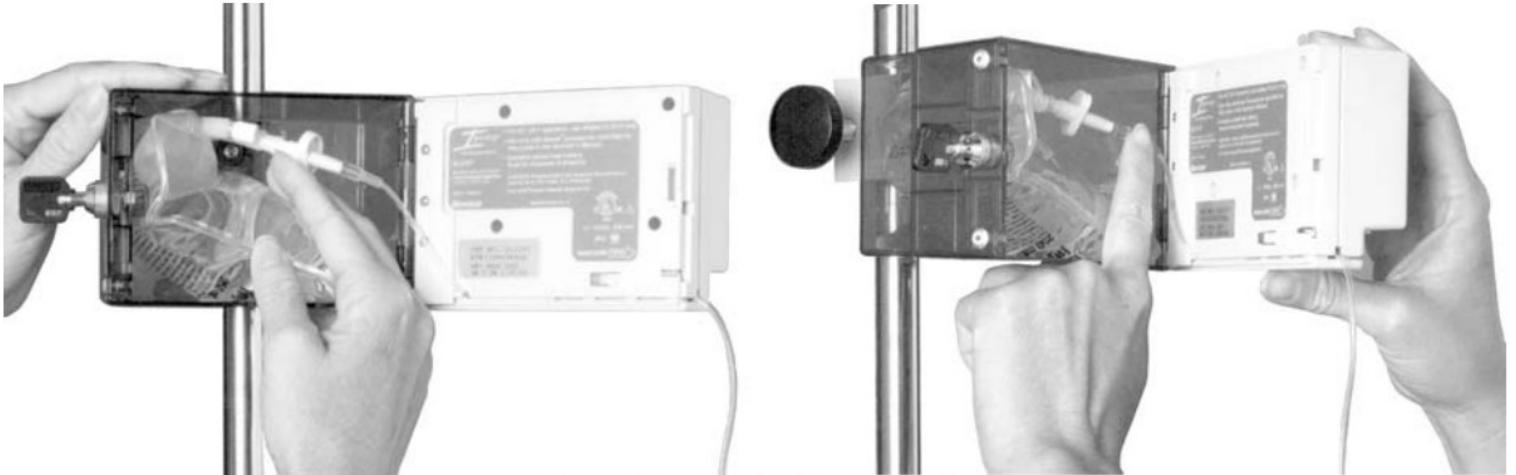


Figure 3-9 Placing the Bag in the Cover

CAUTION

When closing the bag cover, ensure that neither the tubing nor the bag are pinched, twisted, or occluded. Run your fingers around the edges of the bag cover to ensure that no part of the bag or tubing is pinched in the cover. Do not force the bag cover closed if it appears to be obstructed. Clear any obstruction and then close the bag cover.

9. Close and lock the cover, taking care not to pinch the bag or tubing. If the tubing is pinched, an alarm will

sound after the pump is started. If the cover cannot be closed and locked, check the tubing door to be certain it is closed completely.

! WARNING !

If the tubing is pinched by the closed tubing door, resistance to flow may increase and fluid delivery to the patient may be compromised. If this occurs, open the bag cover, reseat the tubing and check the tubing door for proper closure, close the bag cover, then restart the pump.

CAUTION

The time to detect occlusions increases proportionally with a decrease in flow rates. At flow rates below 0.5 mL/hr, an occlusion may not be detected. Baxter recommends that extra care be taken to ensure that neither the tubing nor the bag are pinched, twisted, or occluded.

Changing the Tubing Set and/or Fluid Bag

1. Follow the instructions given in “Loading the Tubing Set,” 3-14, and “Filling and Loading the Fluid Bag,” 3-16, to prepare and install the bag and tubing set.
2. Complete the tasks in the “Action” column of the procedure “Changing the Prescription During Infusion,” 5-35, *except* select FLUID VOLUME at the SELECT ACTION prompt.
3. Enter the correct fluid volume and prime the tubing set, if required (see “Prime the Tubing Set,” 5-16).

! WARNING !

The tubing set **MUST NOT** be connected to the patient while priming.

4. When the pump displays the PUMP READY prompt, press **START** to restart the infusion.

Attaching or Removing the Pump From a Pole (Optional)

Attach the Pump to a Pole

1. Align the pole-mounting clamp below the slide bracket on the back of the pump.
2. Slide the clamp toward the top of the pump until it stops. Make sure that the two holes on the clamp align with the two smaller holes on the bracket.
3. To keep the clamp attached to the pump, insert the two enclosed screws through the clamp and into the holes in the bracket.

! WARNING ! To avoid personal injury, ensure that the IV pole is stable and secure. Ensure that the pole can support the pump, along with any other devices, without tipping or falling. The pole diameter should be between 1.3 and 3.2 cm (0.5 and 1.25 inches).

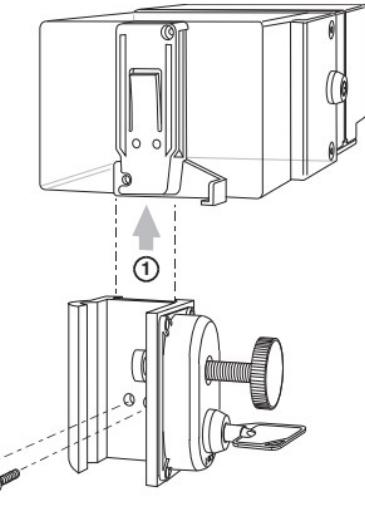


Figure 3-10 Attaching the Clamp

4. Mount the clamp to a stable pole or vertical rail that is 1.3 cm to 3.2 cm (0.5" to 1.25") in diameter and tighten it. If the clamp is detached from the pump, make certain the arrow on the clamp is pointing up.

Note: The pump must be in the clamp before locking the clamp. Failure to do so makes it possible for the pump to be removed without using a key.

5. Lock the clamp by inserting the Pole Clamp key (not the Lock Box key), pushing it in, and rotating it clockwise to the locked position.

Although the clamp may be tightened when it is locked, it cannot be loosened enough to remove it.

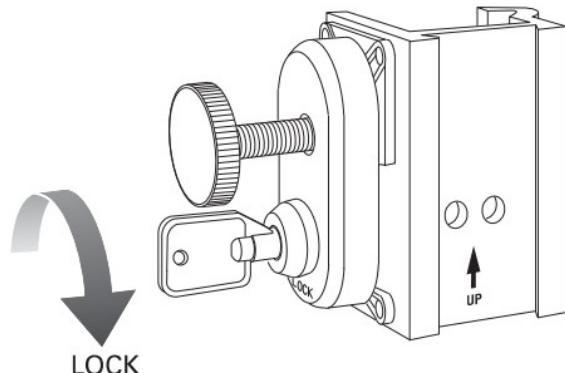


Figure 3-11 Locking the Clamp

Remove the Pump from the Pole

1. Unlock the clamp by inserting the pole-mounting clamp key into the lock on the housing, pushing the key in, and rotating it counter clockwise to the unlocked position.
2. If the clamp has not been screwed onto the pump, slide the pump up and out of the clamp to remove the pump from the clamp. If the clamp has been screwed onto the pump, loosen the clamp by turning the knob counter clockwise to remove both the clamp and the pump from the pole.

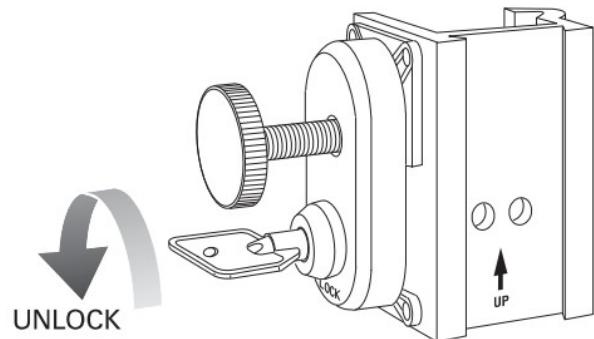
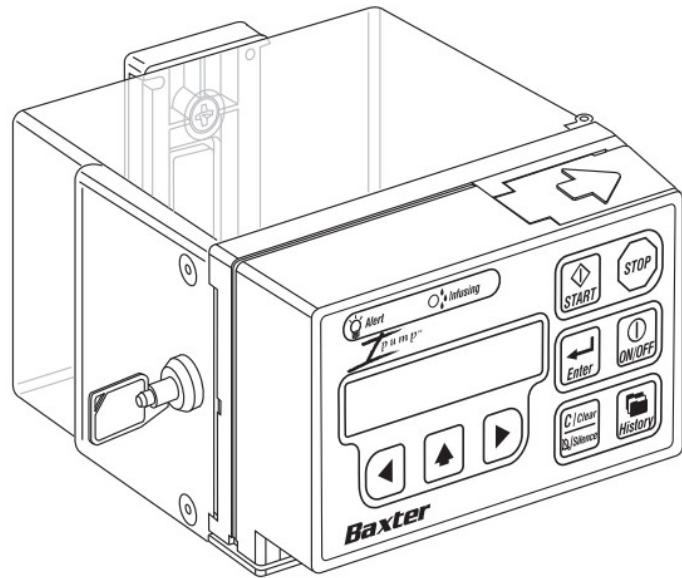


Figure 3-12 Unlocking the Clamp



Chapter 4. Configurable Options

This chapter lists the configurable features and the initial factory settings available for this device. The factory-set defaults can be modified by authorized personnel to meet customer-specific needs as described in the *Ipump Pain Management System Global Configuration Manual*. The pump's configurable features are categorized as:

- **Preferences** – for a particular language, date format, clock type, decimal mark, security method, security code, and identification label (see "Configurable Options -- Preferences," 4-2).
- **Limits** – for the infusion mode, units, dose limit type, max (maximum) PCA dose, max continuous rate, and max bolus dose (see "Configurable Options -- Limits," 4-4).
- **Controls** – for restarting the pump after the bolus and setting the alert silencing time, low-volume alert time, PCA Button status, preventive maintenance alert, upstream occlusion detection, and air detection (see "Configurable Options -- Controls," 4-6).

Table 4-1 Configurable Options—Preferences

| Preferences | Available Settings | Factory Settings |
|-------------|---|------------------|
| Language | ENGLISH SPANISH FRENCH JAPANESE GERMAN DANISH/SWEDISH ITALIAN NONE | NONE |
| Date Format | MM/DD/YY DD/MM/YY YY-MM-DD | MM/DD/YY |

Table 4-1 Configurable Options—Preferences — continued

| Preferences | Available Settings | Factory Settings |
|--|-----------------------------------|---|
| Clock Setting | 12 HOUR 24 HOUR | 12 HOUR NOTE: AM or PM will be displayed when the pump is configured for a 12-hour clock. |
| Decimal Mark This setting is used in countries that use decimal points instead of commas. | POINT (decimal point) COMMA | POINT (decimal point) |
| Security Method This setting determines the security requirements for operating the pump. | KEY+CODE CODE ONLY KEY ONLY | KEY+CODE |
| Security Code | 001 – 999 | 123 |

Table 4-1 Configurable Options—Preferences — continued

| Preferences | Available Settings | Factory Settings |
|--|--|-------------------------|
| Identification Label The Identification Label is a user-defined message that is displayed following the Power On Self Test. | Up to 16 characters (A-Z, 0-9, blank, dash and characters and accents for specific languages such as Japanese characters, German Ä, Ö, Ü, the Danish Å, Å, Ö, and the Spanish Ñ) | None |

Table 4-2 Configurable Options—Limits

| Limits | Available Settings | Factory Settings |
|----------------|--|-------------------------|
| Infusion Modes | PCA Basal+PCA Continuous | All modes enabled |

Table 4-2 Configurable Options—Limits — continued

| Limits | Available Settings | Factory Settings |
|-------------------------|----------------------------------|----------------------------------|
| Infusion Units | mL mg μg | All infusion units types enabled |
| Dose Limit Type | 1 HOUR 4 HOUR PCA DOSES/HR | 1 HOUR |
| Maximum PCA Dose | 0.2 to 9.9 mL | 9.9 mL |
| Maximum Basal Rate | 0.2 to 19.9 mL/hr | 9.9 mL/hr |
| Maximum Continuous Rate | 0.2 to 90.0 mL/hr | 19.9 mL/hr |
| Maximum Bolus Dose | 0.2 to 49.9 mL | 9.9 mL |

Table 4-3 Configurable Options—Controls

| Controls | Available Settings | Factory Settings |
|---|--------------------------------|------------------|
| Restart After Bolus This setting determines whether the pump will begin infusion automatically after completing initial bolus delivery, or whether the operator must press START to begin infusion. | AUTO RESTART MANUAL RESTART | AUTO RESTART |
| Alert Silencing Time | 2, 15, 30 or 60 MIN | 2 MIN |
| Low Volume Alert Time | 30, 60, 90 or 120 MIN | 120 MIN |

Table 4-3 Configurable Options—Controls — continued

| Controls | Available Settings | Factory Settings |
|------------------------------|---------------------------|--|
| PCA Button Status | REQUIRED OPTIONAL | REQUIRED NOTE: In PCA and Basal+PCA modes, the REQUIRED setting requires use of a PCA button to request PCA doses. The OPTIONAL setting allows the use of the START key as an alternative for requesting PCA doses. |
| Preventive Maintenance Alert | 0 (no alert) to 12 MONTHS | 0 (no alert) |
| Upstream Occlusion Detection | ON OFF | ON NOTE: When the pump is configured for upstream occlusion detection, it continuously detects for upstream occlusions throughout an infusion. This is in addition to the upstream occlusion testing performed at the start of an infusion (see “Upstream Occlusion Testing,” 5-18). |

Table 4-3 Configurable Options—Controls — continued

| Controls | Available Settings | Factory Settings |
|--|--|---|
| Air Detection This setting controls the sensitivity of the Air Detection feature. | <p>OFF LOW = 0.5 mL within 0.8 mL of fluid HIGH = 0.1 mL within 0.16 mL of fluid</p> <p>NOTE: During the upstream occlusion test, the Air Detection sensor is turned on regardless of its configured setting. See “Upstream Occlusion Testing” on page 5-18 for more information.</p> | <p>OFF</p> <p>The air sensor will measure the accumulated amount of air detected over an amount of fluid delivered. The amounts of delivered fluid depend on the programmed air bubble size. The air alarm is triggered for a single air bubble greater than the set threshold or an accumulation of air greater than the threshold.</p> <p>! WARNING !</p> <p>The air sensor detects and measures the accumulated amount of air over an amount of fluid delivered. However, the pump may not detect all instances of micro or “champagne” air bubbles.</p> |

Chapter 5. Using the Pump

This chapter describes how to program and use the pump. Because the pump stores patient data, the sequence of the messages displayed on the pump will depend on whether you are programming an infusion for the first time or restarting a pump. The chapter is organized as follows:

- Preliminary Information
- Basic Pump Procedures
- Upstream Occlusion Testing
- Programming the Prescription
- Starting, Stopping, Restarting the Infusion
- Changing the Prescription During Infusion
- Reviewing the Therapy History

! WARNING ! Do not use any pump that has readily apparent defects or damage, including missing or misaligned components, missing display pixels, or missing audio.

Preliminary Information

Select Settings and Enter Values

1. Press the left (\leftarrow) and right (\Rightarrow) keys to position the cursor (\uparrow) under the required digit or selection.

Table 5-1 Cursor Movement

| Cursor Position | Action |
|-----------------|--|
| far-left value | press the \leftarrow key to move (wrap) the \uparrow to the far right. |
| far-right value | press the \Rightarrow key to move (wrap) the \uparrow to the far left. |

2. Press the scroll key ($\hat{\uparrow}$) to select a different value or scroll through available options. To increase the speed of the scrolling, you can:
 - Press and hold $\hat{\uparrow}$ key for more than 1 second to scroll at a rate of 2 characters/second.
 - Release $\hat{\uparrow}$ key and press it again to scroll at the slower rate.
3. Press the **Enter** key to accept the selected value.
4. Press the **Clear/Silence** key to reset numerical values to zero.

Turn on the Back Light

When the pump is powered by the AC adapter, the display and back light will remain on constantly. When operating on battery power only, after a period of inactivity the back light and key pad are deactivated to save energy. To reactivate the back light and key pad, press any key (but not the START key) once, then press the desired action key(s). If the pump is set up for a PCA dose, pressing the START key will initiate a PCA dose, but will not turn on the back light.

Retain Programming Data

The pump automatically saves the prescription settings and tracking information in memory. This information will not be lost if the pump is turned off. If a pump is restarted, the previous prescription can be accessed as described in “Reviewing the Therapy History,” 5-37.

Display the Power Status

The power status of the pump is shown in the upper right hand corner of the display by:

- A battery symbol () to show that the pump is operating on battery power, or
- A plug symbol () to show that the pump is powered by the Baxter AC adapter.

Basic Pump Procedures

Because the pump stores patient data, the sequence of the messages displayed on the pump varies, depending on whether you are setting up an infusion for the first time or restarting a pump. All of these procedures apply to PCA, Basal+PCA, and Continuous infusions. The following procedures include specific instructions and examples that describe how to:

- Turn On the Pump
- Turn Off the Pump
- Select the Language
- Accept or Modify Date and Time Settings
- Unlock and Lock the Cover
- Enter the Security Code
- Use the Initial Prescription
- Select the Mode and Units
- Set the Concentration
- Set the Fluid Volume in the Bag
- Prime the Tubing Set

Note: Before the pump is put in service, it should be configured as necessary to reset any of the default values described in “Configurable Options,” 4-1.

Turn On the Pump

! WARNING ! Do not use any pump that has readily apparent defects or damage, including missing or misaligned components, missing display pixels, or missing audio.

When the pump is turned on, it begins a series of self-diagnostic tests. During these tests, the LEDs flash, and the alarm tone sounds briefly. If the pump fails to display the entire display screen, flash both LEDs, sound a brief alarm tone, or fails the self-test, contact your nearest authorized service center (see “Authorized Service Centers,” 7-1).

| Action | Message Displayed |
|---|--------------------------------|
| 1. Press the ON/OFF key to turn on the pump. | PERFORMING POWER ON SELF TESTS |
| 2. Wait for the self-diagnostic tests to complete. | |

Turn Off the Pump

The prescription and units cannot be changed unless the pump is turned off and then reprogrammed. If the pump is turned off, the current prescription data will be lost.

Note: If it is necessary to retain a patient's history information, you can review and record the history data on the patient's chart or print a hard copy before proceeding with this procedure. See "Reviewing the Therapy History," 5-37.

When turned back on, the pump reverts back to the initial prescription programmed for that patient. See "Restarting the Infusion," 5-33.

| Action | Message Displayed |
|--|--|
| 1. If an infusion is in progress, press STOP twice within 1 second. This will stop the infusion but will not turn off the pump. | KEY+CODE or KEY ONLY: PUMP READY PRESS START CODE ONLY: PUMP READY START OR CLEAR |
| 2. Press the ON/OFF key twice within 1 second to turn the pump off. | |

Select the Language

If the pump is not configured for a particular language, it defaults to the **NONE** option, which allows the user to select the appropriate language: English, Spanish, French, Japanese, German, Danish/Swedish, or Italian. To avoid having to scroll through these languages each time the pump is powered on, set a language as indicated in the *Ipump Pain Management System Global Configuration Manual*.

| Action | Message Displayed |
|--|--|
| 1. Wait for the correct language to appear on the screen. Press Enter to accept the language. OR Wait for the list to repeat or press the \uparrow key to scroll to the correct language if you missed the required entry. | Example: PRESS ENTER FOR \uparrow ENGLISH |
| 2. After the language has been selected, the appropriate software will load. The software version is briefly displayed, followed by a facility-defined identification label (if one has been configured for the pump). | Example: SOFTWARE VERSION X.XX.XX Example: CARDIOLOGY 12 |

Accept or Modify Date and Time Settings

The date may appear as MM/DD/YY, DD/MM/YY, or YY-MM-DD, depending on the configured date format. AM or PM is displayed if the pump is configured for a 12-hour clock but omitted if the pump is configured for a 24-hour clock (military time).

| Action | Message Displayed |
|--|--|
| 1. Wait for the software to load. When the date and time appear: Press Enter to accept the values, and go to the next required procedure. OR Press Clear to modify the values; then go to Step 2. | Example (US): 06/30/99 08:55PM ENTER OR CLEAR Example (EU): 30/06/99 20:55 ENTER OR CLEAR |
| 2. Press the \leftarrow or \rightarrow key to position the \uparrow under the number that you want to change. | Example (US): 06/30/99 08:35PM ↑ SET MONTH Example (EU): 30/06/99 20:35 ↑ SET MONTH |

| Action | Message Displayed |
|--|---|
| 3. Press the ↑ key to select the correct digit. | Example (US): 07/30/99 08:35PM ↑ SET MONTH Example (EU): 30/07/99 20:35 ↑ SET MONTH |
| 4. If you make a mistake, press the: ↑ key again until the correct value appears. OR ⇐ or ⇒ key to reposition the cursor (↑). OR Clear/Silence key to restore the previous values. | Example (US): 10/07/99 08:35PM ↑ SET MONTH Example (EU): 06/30/99 08:35PM ↑ SET MONTH Example (US): 06/30/99 08:35PM ↑ SET DAY |
| 5. Repeat the preceding steps until you have set the month, day, year, hour, and minute. When the values are correct, press Enter . | UNLOCK THE COVER |

Unlock and Lock the Cover

If the pump is configured for the KEY+CODE or KEY ONLY security method, the pump prompts you to UNLOCK THE COVER.

| Action | Message Displayed |
|---|---------------------|
| 1. Place the key inside the lock, twist it one-quarter turn counter clockwise, and open the back cover of the pump. | UNLOCK THE COVER |
| 2. When the cover is unlocked, the pump displays the LOCK THE COVER prompt while sounding a repeating alert tone. | LOCK THE COVER |
| 3. Lock the cover by turning the key clockwise one-quarter turn. | |

Enter the Security Code

If the pump is configured for the KEY+CODE or CODE ONLY, you will be prompted to enter the security code before you can program the prescription.

Note: The pump has a factory-default security code of “123”. See the *Ipump Pain Management System Global Configuration Manual* for directions on how to customize this code.

| Action | Message Displayed |
|---|------------------------------|
| 1. Press the \uparrow key to enter the first number of the security code for the pump. | 000 ENTER CODE \uparrow |
| 2. Press the \Rightarrow key to position the \uparrow under the second number. | 100 ENTER CODE \uparrow |
| 3. Press the \uparrow key to display the second number. If you make a mistake, use the $\uparrow\downarrow$, $\leftarrow\rightarrow$ or \Rightarrow keys to enter the correct value. | 120 ENTER CODE \uparrow |
| 4. Repeat the preceding steps until all of the numbers are entered correctly. Then, press Enter . | 123 ENTER CODE \uparrow |

Use the Initial Prescription

| Action | Message Displayed |
|--|-------------------------|
| <p>1. At the USE INITIAL Rx? prompt, press the ↑ key to display the options YES or NO, then press Enter to select. (If necessary, refer to INITIAL Rx in the Glossary.)</p> <p>If YES is selected, the pump will display the programmed values from the previous initial prescription as default values. Carefully review each screen and press Enter to accept, or modify the prescription if desired by entering different values (for example for the mode, unit, and/or bolus), and then press Enter to accept the new value.</p> <p>If NO is selected, the pump will display SELECT MODE, allowing you to program a new prescription. Refer to page 5-13.</p> <p>NOTE: Rx is a symbol that represents a prescription for drugs or medical devices.</p> <p>! WARNING To help prevent medication errors, Baxter recommends that both the clinician programming the pump and another clinician check the accuracy of prescription and programming information before the infusion is started.</p> | USE INITIAL Rx? ↑ NO |
| <p>2. If necessary, press History to review the previous therapy history as described in the “Reviewing the Therapy History,” 5-37.</p> <p>3. The pump returns to USE INITIAL Rx? following the history review.</p> | |

Select the Mode and Units

Unless the pump is configured for a single mode or a single type of unit, you will be prompted to select the infusion mode and/or units.

| Action | Message Displayed |
|--|--|
| 1. If prompted, press Enter to select the current mode displayed or use the \uparrow key to display the desired mode (PCA, BASAL+PCA, or CONTINUOUS), then press Enter . | Example: SELECT MODE \uparrow PCA |
| 2. Select the units currently displayed, or use the \uparrow key to display the required units (mL, mg or μ g), then press Enter . | Example: SELECT UNITS \uparrow mL |
| 3. If you make a mistake, press the \uparrow key until the correct selection appears. | |
| 4. When the correct selection is displayed, press Enter . | |

Set the Concentration

The units displayed on the pump's LCD are determined by the selected programming unit and mode. If the current (initial) prescription settings are being used, that concentration setting is displayed instead of zeroes. If mL units are selected, you do not have to enter a concentration.

| Action | Message Displayed |
|---|---|
| 1. Use the \Leftarrow or \Rightarrow keys and \uparrow key to set the correct concentration. | 00.0 mg/mL SET \uparrow CONC. |
| 2. If you make a mistake, press the: \uparrow key until the correct value appears. OR \Leftarrow or \Rightarrow key to reposition the \uparrow . OR Clear/Silence key to reset the previous value to 0. | 000 μ g/mL SET \uparrow CONC. |
| 3. Press Enter when the desired value is displayed. | Example: 10.0 mg/mL SET \uparrow CONC. 100 μ g/mL SET \uparrow CONC. |

Set the Fluid Volume in the Bag

Before continuing with prescription entry, you must set the fluid volume in the bag.

| Action | Message Displayed |
|--|--|
| 1. Press the \Leftarrow or \Rightarrow key to position the \uparrow . | 0000 mL SET \uparrow FLUID VOLUME |
| 2. Press the Clear/Silence key to reset the values to zero or the previous setting. If desired, press the \uparrow key as necessary to set the volume. | |
| 3. Press the Enter key to set the value. | |

Prime the Tubing Set

The tubing set must be disconnected from the patient before priming. As a security measure, you will not be allowed to prime the tubing set more than 10 times without entering a security code or using the key to demonstrate authority to use the pump. While priming is in progress, the pump displays the amount being delivered. After priming is completed, the pump shows the total priming volume.

! WARNING ! The tubing set MUST NOT be connected to the patient while priming.

Note: When the pump is priming the tubing set, the air-in-tubing alarm is disabled.

Note: To skip priming, press **Enter**. However, if air is detected in the tubing set during the upstream occlusion test at the start of the infusion, the operator will be required to prime the tubing set at that time. See "Upstream Occlusion Testing," 5-18.

| Action | Message Displayed |
|--|------------------------------------|
| 1. Press the START key to prime the tubing set. | START TO PRIME ENTER TO PROCEED |
| 2. Wait for the pump to begin priming the tubing set. The priming continues until 0.5 mL is delivered or STOP is pressed. | Example: PRIMING 00.2 mL |

| Action | Message Displayed |
|--|--------------------------------------|
| 3. Observe the PRIMING TOTAL message. | Example: PRIMING TOTAL 01.5 mL |
| 4. Wait a few seconds until the pump returns to the START TO PRIME/ENTER TO PROCEED prompt. | START TO PRIME ENTER TO PROCEED |
| 5. Repeat priming as many times as necessary until the tubing set is fully primed. NOTE: After 10 priming steps (that is, when 5 mL is delivered), the clinician must enter the security code or use the key to demonstrate authority to use the pump. | |
| 6. Press Enter to continue prescription entry. | |

Upstream Occlusion Testing

If the pump is configured for upstream occlusion detection (see “Configurable Options,” 4-1), the pump performs an automatic upstream occlusion test the first time START is pressed to begin an infusion after power-on, and whenever START is pressed to start the infusion after the tubing door has been opened and closed. During the test, the screen displays TESTING UP OCCLUSION, and the **Alert** LED flashes red. The test takes approximately 15 seconds.

Note: During the start of therapy, the Downstream Occlusion Detection feature is disabled while the pump is performing the Automatic Upstream Occlusion Test. Make sure the tubing set is not kinked or blocked both upstream and downstream of the pump. The maximum infusion pressure generated prior to alarm activation may be exceeded if there is a kink or blockage during the Upstream Occlusion Test. See "Maximum Infusion Pressure Generated" on page 9-2.

If no upstream occlusion is detected, the pump passes the test and the infusion (or bolus, if one is programmed) will begin automatically.

If an upstream occlusion is detected during the test, the UPSTREAM OCCLUSION alarm is triggered. See Table 6-2 "Alarm Messages and Responses," on page 6-18 for information on resolving this alarm.

Note: The pump will not begin infusing until it has successfully passed the upstream occlusion test. If an occlusion is detected, the test will need to be repeated until it passes successfully. See Table 6-2 on page 6-18 for more information.

During the upstream occlusion test, the Air Detection sensor is turned on even if the sensor is configured to be OFF. If air is detected during the test, the SET NOT PRIMED alarm is triggered. See Table 6-2 on page 6-15 for information on resolving this alarm.

! WARNING ! The tubing set MUST NOT be connected to the patient while priming.

Programming the Prescription

These procedures cover how to program PCA, Basal+PCA, and Continuous prescriptions. After you select PCA, Basal+PCA, or Continuous, complete all applicable tasks. The tasks covered in this section include:

- Programming the PCA Dose
- Setting the PCA Delay Period
- Programming the Basal Rate
- Setting the Dose Limit
- Programming the Continuous Rate
- Programming the Bolus Dose
- Programming a Supplemental (Clinician) Bolus

All of the units presented in this section are provided only as examples. The actual units displayed are determined by the selected programming units (mL, mg, or μ g). If the initial prescription settings are being used, those values will be displayed instead of zeroes.

Programming the PCA Dose

Note: Skip this procedure if programming a Continuous prescription.

The PCA dose is the programmed volume of the drug to be delivered when requested by the patient.

Note: The pump produces an audible tone whenever the PCA button is pressed.

| Action | Message Displayed |
|---|--------------------------------------|
| 1. Use the \Leftarrow and \Rightarrow keys and \uparrow to program the PCA dose. | 0.0 mL SET \uparrow PCA DOSE |
| 2. If necessary, press the Clear/Silence key to reset the displayed value to zero. | |
| 3. Press Enter when the desired value is displayed. | |

Setting the PCA Delay Period

Note: Skip this procedure if programming a Continuous prescription.

The first delay period is measured from the start of the infusion program to the start of the first PCA dose. Subsequent delay periods begin with the start of delivery of each PCA dose. During the delay period, another PCA dose may not be started even if a PCA dose is interrupted.

Important: The delay time must elapse before a patient attempt will result in an injection, whether or not a bolus dose was given. This delay allows any bolus to take effect before allowing an injection.

| Action | Message Displayed |
|--|-------------------------------------|
| 1. Use the \Leftarrow and \Rightarrow keys and \uparrow to set the PCA delay period. | 000 MINUTES \uparrow SET DELAY |
| 2. If necessary, press the Clear/Silence key to reset the displayed value to zero. | |
| 3. Press Enter when the desired value is displayed. | |

Programming the Basal Rate

Note: Skip this procedure if programming a PCA or Continuous prescription.

| Action | Message Displayed |
|---|---|
| 1. Use the \leftarrow and \Rightarrow keys and \uparrow to program the basal rate. | 000.00 mg/hr SET \uparrow BASAL RATE |
| 2. If necessary, press the Clear/Silence key to reset the displayed value to zero. | |
| 3. Press Enter when the desired value is displayed. | |

Setting the Dose Limit

Note: Skip this procedure if programming a Continuous prescription.

The pump will display a 1-hour, 4-hour, or maximum PCA dose limit, depending on the configuration. If the 1-hour or 4-hour limit is reprogrammed, a new time period is started and the dosage delivered is restarted from zero. If the maximum PCA dose limit per hour is reprogrammed, a new time period is started, but the dose that was stopped before the delivery was completed will be counted towards the dose per hour limit in the new time period.

| Action | Message Displayed |
|---|---|
| 1. Use the \leftarrow and \Rightarrow keys and \uparrow to set the dose limit. NOTE: The maximum 1- and 4-hour limit that can be programmed is the total amount of medication called for in the programmed prescription. The minimum 1- and 4-hour limit for a Basal+PCA prescription is a factor of the basal rate plus the volume of at least one PCA dose. | 000.0 mg SET ↑ 1 HR LIMIT 000.00 mg SET ↑ 4 HR LIMIT 00 SET MAX PCA ↑ DOSES/HR |
| 2. If necessary, press the Clear/Silence key to reset the displayed value to zero. | |

| Action | Message Displayed |
|--|--|
| 3. Press Enter when the desired value is displayed. | <p>Example:</p> <p>010.0 mg SET ↑ 1 HR LIMIT</p> <p>010.00 mg SET ↑ 4 HR LIMIT</p> <p>01 SET MAX PCA ↑ DOSES/HR</p> |

Programming the Continuous Rate

Note: Skip this procedure if programming a PCA or Basal+PCA prescription.

| Action | Message Displayed |
|---|--|
| 1. Use the \leftarrow and \Rightarrow keys and \uparrow to program the continuous rate. | 000.00 mg/hr SET \uparrow CONTINUOUS RATE |
| 2. If necessary, press the Clear/Silence key to reset the displayed value to zero. | |
| 3. Press Enter when the desired value is displayed. | |

Programming the Bolus Dose

The bolus dose is either programmed and delivered automatically at the beginning of therapy, or initiated by the clinician during the course of therapy as a supplemental (clinician) bolus [see “Programming a Supplemental (Clinician) Bolus,” 5-28]. If a programmed bolus dose has not been started, the pump will display the programmed dosage instead of zeroes.

| Action | Message Displayed |
|--|-------------------------------------|
| 1. Use the \leftarrow and \rightarrow keys and \uparrow to program the bolus dose. NOTE: If no bolus is desired, enter zero. | 0000.0 mg SET \uparrow BOLUS |
| 2. If necessary, press the Clear/Silence key to reset the displayed value to zero. | |
| 3. Press Enter when the desired value is displayed. | 0100.0 mg SET \uparrow BOLUS |
| 4. Connect the pump tubing set to the patient’s access device. | START BEGINS Rx ENTER REVIEWS Rx |

| Action | Message Displayed |
|---|---|
| <p>5. Press START. The automatic upstream occlusion test is performed (see “Upstream Occlusion Testing,” 5-18). During the test, the Alert LED flashes red.</p> <p>Upon successful completion of the test, the bolus starts, and the Infusing LED flashes green.</p> <p>NOTE: The pump will not begin infusing until it has successfully passed the upstream occlusion test. If an UPSTREAM OCCLUSION or SET NOT PRIMED alarm occurs, the test must be repeated until it passes successfully. See Table 6-2, "Alarm Messages and Responses," on pages 6-18 and 6-15 for more information.</p> | TESTING UP OCCLUSION Example: BOLUS INFUSING 1000.0 mg |
| <p>6. Wait until the bolus delivery is completed, or press STOP twice in 1 second to stop the infusion.</p> | Example: BOLUS DONE 1000.0 mg |

Programming a Supplemental (Clinician) Bolus

If a bolus is interrupted, it cannot be restarted automatically. To administer additional bolus volumes, you must reprogram the bolus.

| Action | Message Displayed |
|--|--|
| 1. Press STOP twice to interrupt the infusion or bolus. | KEY+CODE or KEY ONLY: PUMP READY PRESS START CODE ONLY: PUMP READY START OR CLEAR |
| 2. If the pump is configured as KEY+CODE or KEY ONLY, unlock and lock the fluid bag cover. If the pump is configured as CODE ONLY, press Clear/Silence . If the pump is configured as KEY+CODE or CODE ONLY, enter the correct security code at the ENTER CODE OR START prompt, and press Enter . | PUMP READY PRESS START PUMP READY START OR CLEAR 000 ENTER CODE ↑ OR START |

| Action | Message Displayed |
|--|--|
| 3. At the SELECT ACTION prompt, use the \uparrow key to display the SET BOLUS prompt, then press Enter . | SELECT ACTION SET BOLUS |
| 4. At the SET BOLUS prompt, use the \leftarrow and \rightarrow keys and \uparrow key to set the desired bolus dose. Press Clear/Silence to make the displayed value zero. Press Enter when the desired value is displayed. | 00.0 mL SET ↑ BOLUS |
| 5. Press Enter to review or change the prescription. See “Review the Prescription,” 5-37 or “Changing the Prescription During Infusion,” 5-35. OR Press START to begin infusing the supplemental (clinician) bolus. | START BEGINS Rx ENTER REVIEWS Rx |
| 6. If you pressed START , the pump resumes the infusion and displays BOLUS INFUSING. The bolus delivery will continue until the bolus dose is delivered or STOP is pressed twice in 1 second. | Example: BOLUS INFUSING 0001.3 mg |

| Action | Message Displayed |
|--|---|
| 7. When the bolus delivery is completed, the pump displays a BOLUS DONE message. | Example: BOLUS DONE 002.0 mg |
| 8. Press START to resume the infusion. NOTE: If the pump configuration specifies automatic start after bolus, infusion will resume automatically in approximately 10 seconds. | PCA BASAL+PCA |

Starting, Stopping, Restarting the Infusion

Starting the Infusion

| Action | Message Displayed |
|--|--|
| <p>1. Press START. The automatic upstream occlusion test is performed (see “Upstream Occlusion Testing,” 5-18). During the test, the Alert LED flashes red.</p> <p>Upon successful completion of the test, the infusion starts, and the Infusing LED flashes green.</p> <p>NOTE: The pump will not begin infusing until it has successfully passed the upstream occlusion test. If an UPSTREAM OCCLUSION or SET NOT PRIMED alarm occurs, the test must be repeated until it passes successfully. See Table 6-2, "Alarm Messages and Responses," on pages 6-18 and 6-15 for more information.</p> <p>NOTE: If the pump is configured for an automatic start after bolus, the infusion will begin immediately after the delivery of the bolus if one has been programmed.</p> | <p>TESTING UP OCCLUSION</p> <p>Then: PCA</p> <p>BASAL+PCA</p> <p>CONTINUOUS 00.0 mg/hr</p> |

Stopping the Infusion

| Action | Message Displayed |
|--|---|
| <p>1. Press STOP twice to interrupt the infusion or bolus.</p> <p><u>Sleep Mode Option (used to interrupt then resume the current infusion)</u></p> <ol style="list-style-type: none">1. Open the battery compartment door and remove the battery. When the battery is removed, a chirping alert sound will be heard.2. Position the battery so that the (+) and (-) poles are facing out of the pump, and then slide the battery back into the compartment.3. Close the battery compartment door.4. Press Clear/Silence to silence the alert sound.5. To resume the current infusion, open the battery compartment door and remove the battery.6. Insert the battery with the (+) and (-) poles properly facing into the pump, and then slide the battery back into the compartment.7. Close the battery compartment door.8. Press ON/OFF to turn the pump back on, and follow the prompts to resume the infusion. | <p>KEY+CODE or KEY ONLY: PUMP READY PRESS START</p> <p>CODE ONLY: PUMP READY START OR CLEAR</p> |

Restarting the Infusion

| Action | Message Displayed |
|--|---|
| <p>1. If the pump is configured as KEY+CODE or KEY ONLY, press START to restart the infusion, or unlock and lock the fluid bag cover to access the SELECT ACTION options.</p> <p>If the pump is configured as CODE ONLY, press START to restart the infusion, or press Clear/Silence to access the SELECT ACTION options.</p> <p>If the pump is configured as KEY+CODE or CODE ONLY, at the ENTER CODE OR START prompt press START to restart the infusion, or enter the correct security code and press Enter to access the SELECT ACTION options.</p> | PUMP READY PRESS START PUMP READY START OR CLEAR 000 ENTER CODE ↑ OR START |

| Action | Message Displayed |
|---|--|
| <p>2. When the pump displays the SELECT ACTION prompt, use the ↑ key to select one of the following options, then press Enter:</p> <p>FLUID VOLUME to enter the fluid volume after changing the fluid bag.</p> <p>OR</p> <p>SET BOLUS to program a supplemental (clinician) bolus dose. See “Programming a Supplemental (Clinician) Bolus,” 5-28.</p> <p>OR</p> <p>CHANGE Rx to modify the prescription. See “Changing the Prescription During Infusion,” 5-35.</p> <p>OR</p> <p>START INFUSION to restart the infusion.</p> | SELECT ACTION ↑ FLUID VOLUME SELECT ACTION ↑ SET BOLUS SELECT ACTION ↑ CHANGE Rx SELECT ACTION ↑ START INFUSION |

Changing the Prescription During Infusion

The prescription and units cannot be changed unless the pump is turned off and then reprogrammed. If it is necessary to retain a patient's history information, you can review and record the history data on the patient's chart or print a hard copy before proceeding with this procedure. See "Reviewing the Therapy History," 5-37. To program a supplemental (clinician) bolus, see "Programming a Supplemental (Clinician) Bolus," 5-28.

| Action | Message Displayed |
|--|--|
| 1. Press STOP twice to interrupt the infusion or bolus. | KEY+CODE or KEY ONLY: PUMP READY PRESS START CODE ONLY: PUMP READY START OR CLEAR |

| Action | Message Displayed |
|--|---|
| <p>2. If the pump is configured as KEY+CODE or KEY ONLY, unlock and lock the fluid bag cover.</p> <p>If the pump is configured as CODE ONLY, press Clear/Silence.</p> <p>If the pump is configured as KEY+CODE or CODE ONLY, enter the correct security code at the ENTER CODE OR START prompt, and press Enter.</p> | PUMP READY PRESS START PUMP READY START OR CLEAR 000 ENTER CODE ↑ OR START |
| 3. At the SELECT ACTION prompt, use the ↑ key to display the CHANGE Rx prompt, then press Enter . | SELECT ACTION CHANGE Rx |
| 4. Use the ← and → keys and ↑ to program the new prescription. See “Programming the Prescription,” 5-19. | |
| 5. Press START to begin the infusion. | START BEGINS Rx ENTER REVIEWS Rx |

Reviewing the Therapy History

The pump retains a record of the previous prescription and therapy history in memory until it is modified or the pump is reconfigured. This section describes the following:

- Review the Prescription
- Navigate Through Patient History
- View a Patient's History
- History Not Available Message
- Optional History Printout

All of the totals displayed reflect current information at the time that they are displayed. The date and time formats are determined by the configuration of the pump, and the units displayed are the programmed units in mL, mg, or µg.

Review the Prescription

To review a prescription, you can view the patient's prescription details as described in "View a Patient's History," 5-40, or as part of the bolus entry procedure. The following procedure describes prescription review as part of programming a bolus.

| Action | Message Displayed |
|--|--|
| 1. At the SET BOLUS prompt, use the \leftarrow and \Rightarrow keys and \uparrow to program the bolus dose. | 00.0 mL ↑ SET BOLUS |
| 2. Press Enter when the desired values are displayed. | START BEGINS Rx ENTER REVIEWS Rx |
| 3. At the START BEGINS Rx, ENTER REVIEWS Rx prompt, press Enter to review the prescription. The messages displayed will vary depending upon whether a prescription has been started. If a prescription has not been started, the pump will prompt you to begin the steps for setting up the pump for use. See “Select the Mode and Units,” 5-13. If a prescription has been started, you can stop the pump and review or change the prescription that was previously programmed. See “Changing the Prescription During Infusion,” 5-35. | SELECT MODE ↑ PCA SELECT ACTION CHANGE Rx |

Navigating Through Patient History

Note: The pump history feature is quite extensive. To navigate to a specific category of history (i.e., shift history), press the ↑ key at the first screen of each category (as shown in column two below).

| From the main category of: | Press the ↑ key to | Press the ⇒ key to | Press the ← key to |
|----------------------------|--|--|--|
| THERAPY STARTED | advance to SHIFT HISTORY | scroll through the history review screen by screen | Not applicable. Press History to exit from the history feature. |
| SHIFT HISTORY | advance to PRESCRIPTION DETAILS | scroll through the shift history screen by screen | return to THERAPY STARTED |
| PRESCRIPTION DETAILS | advance to HOURLY HISTORY | scroll through the prescription detail screen by screen | return to SHIFT HISTORY |
| HOURLY HISTORY | advance to EVENT HISTORY | scroll through the hourly history screen by screen | return to PRESCRIPTION DETAILS |
| EVENT HISTORY | advance to END OF HISTORY | scroll through the event history screen by screen | return to HOURLY HISTORY |
| END OF HISTORY | Not applicable. Press History to exit from the history feature. | Not applicable. Press History to exit from the history feature. | return to EVENT HISTORY |

NOTE: Press **History** at any time to exit from the history feature.

NOTE: Within the sub-screens of each category, pressing the ← key will display the previous screen.

NOTE: If the ⇒ or ← keys are pressed and held, the detailed history scrolls quickly.

View a Patient's History

This section provides a detailed description of the history screens.

| Action | Message Displayed |
|---|--|
| 1. Press History during an infusion or whenever one of the messages shown in the next column is displayed. | PUMP READY PRESS START |
| 2. If a patient's history is available, the date and time of the start of infusion appears on the screen. Go to Step 4. | PUMP READY START OR CLEAR |
| 3. If a patient's history is not available, see "History Not Available Message," 5-49. | REVIEW HISTORY OR PRESS ENTER |
| Note: Pressing Enter at the REVIEW HISTORY or PRESS ENTER message clears the history. | ENTER CODE ENTER CODE OR START USE INITIAL Rx? ↑ YES |
| NOTE: Several date/time format options are available for the pump (see "Configurable Options," 4-1). The examples presented herein use the pump default settings of MM/DD/YY format using a 12 hour clock. | |

| Action | Message Displayed |
|--|--|
| <p>4. The pump records the total, dates, number, and amount of each patient's prescription. The type and sequence of the messages are directly dependent on the programmed prescription. When the THERAPY STARTED message appears:</p> <ul style="list-style-type: none"> 4.1 Press the \Rightarrow key to scroll through the history review screens. 4.2 Press the \Leftarrow key to go back to the previous history screen or the start of the previous group of screens. 4.3 Press \uparrow to proceed to the SHIFT HISTORY group messages. 4.4 Press the History key again to exit the history review at any time. | Example: THERAPY STARTED 03/10/99 08:11AM |
| <p>5. As you scroll, the following messages are displayed:</p> <ul style="list-style-type: none"> 5.1 TOTAL GIVEN, including any PCA, BASAL+PCA, CONTINUOUS, and bolus infusions. | Example: 53.3 mg TOTAL GIVEN |

| Action | Message Displayed |
|--|---|
| 5.2 For PCA infusions, the recorded number of total injections (TOTAL INJ) administered and total dose attempts (TOTAL ATT). Partial PCA doses are included in the TOTAL INJ count. A partial dose can occur when a dose is interrupted by an occlusion, or when the dose is interrupted because the 1-hour limit or 4-hour limit has been reached. | Example: 0008 TOTAL INJ 0010 TOTAL ATT |
| 5.3 For bolus infusions, the total of the initial and supplemental (clinician) bolus infusions. | Example: 0012.0 mL BOLUS INFUSED |
| 5.4 The FLUID VOLUME REMAINING | Example: 0039.3 mL FLUID VOLUME REMAINING |

| Action | Message Displayed |
|--|-------------------|
| 6. The SHIFT HISTORY group messages provide specific pump infusion information for a particular shift. A new shift is started whenever the operator clears the shift totals. After reviewing the information, you can delete the data and initiate a new shift. At the SHIFT HISTORY message: 6.1 Press the \Rightarrow key to scroll through the history review screens. 6.2 Press the \Leftarrow key to go back to the previous history screen or group of screens. 6.3 Press the History key again to exit the history review at any time. 6.4 Press \uparrow to proceed to the PRESCRIPTION DETAILS group messages. | SHIFT HISTORY |

| Action | Message Displayed |
|--|--|
| 7. As you scroll, the following messages are displayed: | |
| 7.1 The date and time of the start of the shift. (A new shift is started whenever the operator clears the shift totals.) | Example: SHIFT STARTED 03/17/99 12:00AM |
| 7.2 For PCA doses only, the total injections (TOTAL INJ) administered and total attempts (TOTAL ATT) recorded per shift. | Example: 0004 TOTAL INJ 0004 TOTAL ATT |
| 7.3 The Shift Total for any PCA, Basal+PCA, Continuous, or bolus infusions. | Example: 0031.5 mL SHIFT TOTAL |
| 8. After you view the SHIFT TOTAL screen, you may (as an option) choose to: | SHIFT TOTALS CLEARED |
| 8.1 Press Clear/Silence to clear the totals and begin a new shift. | |
| 8.2 Wait for the INITIAL SETTINGS of the prescription to appear on the screen. | |

NOTE: Pressing **Clear/Silence** will reset the total infused and the "injections versus attempts" to zero and set the time and date of the new shift to the time/date that the pump was cleared.

| Action | Message Displayed |
|--|---|
| 9. Press the \Rightarrow key to view the following PRESCRIPTION DETAILS (or press \uparrow to proceed to the HOURLY HISTORY group messages): | PRESCRIPTION DETAILS |
| 9.1 Concentration | Example: 05.0 mg/mL CONCENTRATION |
| 9.2 Dose | Example: 6.0 mg PCA DOSE |
| 9.3 Delay | Example: 003 MINUTES DELAY |
| 9.4 Rate settings | Example: 004.00 mg/hr BASAL RATE |

| Action | Message Displayed |
|--|--|
| 10. The HOURLY HISTORY group of screens is displayed only if PCA doses were allowed at some time during the therapy. For each 24-hour period, three screens per hour are generated. At the HOURLY HISTORY message, press the \Rightarrow key to scroll through the following screens (or press \uparrow to proceed to the EVENT HISTORY group messages): | HOURLY HISTORY |
| 10.1 The hour of the dosage. | Example: 11:30 - 12:00AM |
| 10.2 The number of PCA doses administered and the number requested during the hourly period. | Example: 0004 INJECTIONS 0004 ATTEMPTS |
| 10.3 The cumulative total infused at the end of the hourly period, including any bolus, PCA, and Basal+PCA infusions. | Example: 0031.5 mL GIVEN AS OF 12:00AM |
| 11. The EVENT HISTORY group displays a chronological list of events that occurred during the therapy. This group begins with the message EVENT HISTORY and ends with the message END OF HISTORY. (Press \uparrow to proceed directly to END OF HISTORY.) | EVENT HISTORY |

| Action | Message Displayed |
|---|---|
| 12. Press the \Rightarrow key to display the following types of events: | |
| 12.1 Date and time cover was unlocked. | Example: COVER UNLOCKED 03/17/99 12:15PM |
| 12.2 Date and time infusion was started. | Example: START INFUSION 03/17/99 01:20PM |
| 12.3 Date and time infusion was stopped. | Example: STOP INFUSION 03/18/99 02:20PM |
| 12.4 Date and time bolus was started. | Example: START BOLUS 03/17/99 12:20AM |
| 12.5 Total bolus infused. | Example: 008.0 mg BOLUS DONE |

| Action | Message Displayed |
|--|--|
| 12.6 Date and time 1-hour limit, 4-hour limit or max doses per hour limit was reached. | Example: DOSE LIMIT 03/16/99 11:58PM |
| 12.7 Date and time and type of alarm. | Example: AIR IN TUBING 03/17/99 09:30AM |
| 12.8 Change to prescription value. | NOTE: This information is only displayed in the printout of the Patient History. See "Optional History Printout," 5-49. |
| 12.9 Date and time when the infusion ended. | Example: THERAPY ENDED AT 03/17/99 09:30AM |
| 12.10 End of the patient's history review. | END OF HISTORY |

History Not Available Message

If the pump displays HISTORY NOT AVAILABLE when the **History** key is pressed, the history may have been erased if:

- A new prescription was entered, but not yet started, for a PCA, Basal+PCA, or Continuous mode infusion.

OR

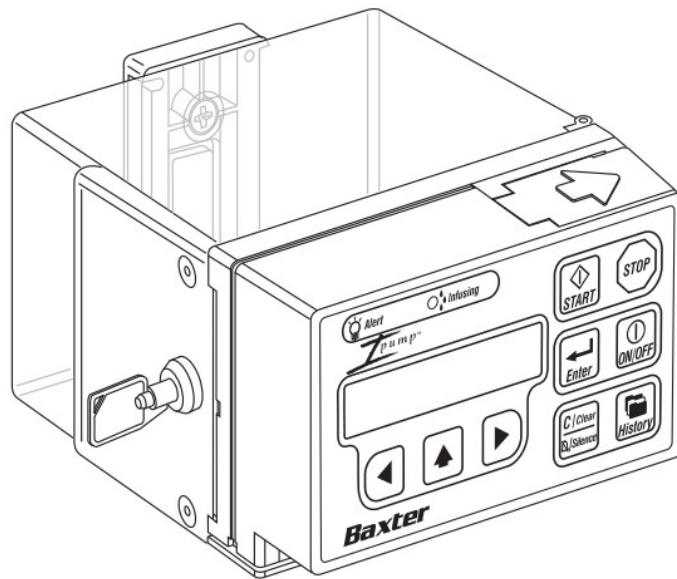
- The pump's configuration was modified.

Optional History Printout

The therapy history data can be printed using an optional printer and printer adapter. Some information, such as changes made to prescription values, can only be viewed in a printout. Contact your local Baxter Service Center for details.

Note: DO NOT connect the printer adapter and printer to the pump while the pump is infusing.

Note: Make sure the printer adapter contains fresh batteries to ensure optimal communications between the pump and the printer.



Chapter 6. Alerts and Alarms

Audible tones for alerts and alarms can be silenced by pressing the **Clear/Silence** key. For alerts, the audible tones will resume after the time period defined by the Alert Silencing Time setting (see “Configurable Options,” 4-1). For alarms, the tones will resume after two minutes.

An alarm, unlike an alert, requires immediate attention because it stops the infusion. Alerts and alarms are indicated by:

- Flashing red **Alert** LED indicator
- Audible tone consisting of a single or repeating tone of one long beep followed by three short beeps
- Screen message that describes the cause of the alert or alarm.

Note: If the pump is battery operated, the alert or alarm message will not be displayed until you press a key.

Alerts

Alert messages are described in this section with step-by-step procedures for resolving the alert. These alert messages are organized numerically and then alphabetically.

Table 6-1 Alert Messages and Responses

| Alert Message | Situation/Action |
|-------------------------|--|
| 1 HOUR LIMIT REACHED | <p>Situation: The volume delivered has reached the programmed 1-hour limit and further fluid delivery has been stopped. Pump operation is interrupted.</p> <p>Action:</p> <ol style="list-style-type: none">1. Press Clear/Silence to cancel the alert.2. Check the prescription and verify that the correct parameters have been entered. Evaluate the current prescription. Infusion and/or availability of PCA (as programmed) will resume when the 1-hour period expires.3. If the patient requires an additional drug dosage after the infusion has been interrupted by the 1-hour limit, then:<ul style="list-style-type: none">■ administer a bolus dose (see “Programming the Bolus Dose,” 5-26) or■ reprogram an increased 1-hour limit.If the 1-hour limit is reprogrammed, the pump starts a new 1-hour accounting period. Changes to other prescription parameters will not start a new 1-hour accounting period. |

Table 6-1 Alert Messages and Responses — continued

| Alert Message | Situation/Action |
|-------------------------|--|
| 4 HOUR LIMIT REACHED | <p>Situation: The volume delivered has reached the programmed 4-hour limit and further fluid delivery has been stopped. Pump operation is interrupted.</p> <p>Action:</p> <ol style="list-style-type: none">1. Press Clear/Silence to cancel the alert.2. Check the prescription and verify that the correct parameters have been entered. Evaluate the current prescription. Infusion and/or availability of PCA (as programmed) will resume when the 4-hour period expires.3. If the patient requires an additional drug dosage after the infusion has been interrupted by the 4-hour limit, then:<ul style="list-style-type: none">■ administer a bolus dose (see “Programming the Bolus Dose,” 5-26) or■ reprogram an increased 4-hour limit.If the 4-hour limit is reprogrammed, the pump starts a new 4-hour accounting period. Changes to other prescription parameters will not start a new 4-hour accounting period. |

Table 6-1 Alert Messages and Responses — continued

| Alert Message | Situation/Action |
|---|---|
| <p>AC ADAPTER FAILURE Or AC FAILURE</p> | <p>Situation: The AC adapter is not functioning correctly. If another action is occurring at the same time, the pump displays the message AC FAILURE in the second line of the screen.</p> <p>NOTE: The pump will continue to operate on battery power if the AC adapter fails. If the battery power is low, the AC ADAPTER FAILURE condition could become an ALARM and stop the infusion.</p> <p>Action:</p> <ol style="list-style-type: none"><li data-bbox="419 574 1477 653">1. Make sure the AC adapter is plugged into the pump and the power outlet properly.<li data-bbox="419 673 875 707">2. Try a different power outlet.<li data-bbox="419 728 1200 761">3. If the alert condition persists, replace the AC adapter. |

Table 6-1 Alert Messages and Responses — continued

| Alert Message | Situation/Action |
|---|---|
| BATTERY IS MISSING Or BATTERY MISSING | <p>Situation: The pump is powered by the AC adapter and no battery is inserted. If another action is occurring at the same time, the pump displays the message BATTERY MISSING on the second line of the screen.</p> <p>Action: Follow the directions for replacing the battery under “Installing and Changing the Battery,” 3-2.</p> |
| BATTERY VOLTAGE IS LOW | <p>Situation: The pump has just completed the power on self-test and the battery power is low. Three short tones are sounded.</p> <p>NOTE: If the battery voltage reaches a low level during an infusion, the BATTERY VOLTAGE IS LOW condition could become an ALARM.</p> <p>Action:</p> <ol style="list-style-type: none"><li data-bbox="419 714 1547 786">1. Press Clear/Silence during the alert to silence the audio for 2 minutes, regardless of the Alert Silencing Time configuration setting.<li data-bbox="419 806 1547 878">2. Replace the battery as soon as possible as specified in “Installing and Changing the Battery,” 3-2. |

Table 6-1 Alert Messages and Responses — continued

| Alert Message | Situation/Action |
|------------------------|--|
| BOLUS DONE | <p>Situation: A bolus has completed, the pump is configured for manual start after bolus, and neither the START or the Enter key has been pressed for 1 minute.</p> <p>Action: Press Enter or START to start the infusion.</p> |
| CODE INCORRECT | <p>Situation: An invalid security code has been entered.</p> <p>Action: Enter the correct code.</p> |
| FLUID VOLUME IS LOW | <p>Situation: The calculated fluid volume remaining in the bag equals or is less than the amount required for configured time parameters.</p> <p>Action: Prepare to replace the fluid bag if necessary.</p> |
| LOW BATTERY | <p>Situation: The battery power is low. A repeating alert tone is sounded. Remaining battery life is approximately 6 hours or less when running the pump at 1 mL/hr.</p> <p>Action:</p> <ol style="list-style-type: none"><li data-bbox="419 769 1547 840">1. Press Clear/Silence during the alert to silence the audio for 60 minutes, regardless of the Alert Silencing Time configuration setting.<li data-bbox="419 850 1547 922">2. Replace the battery as soon as possible as specified in “Installing and Changing the Battery,” 3-2. |

Table 6-1 Alert Messages and Responses — continued

| Alert Message | Situation/Action |
|-------------------------------|---|
| PCA BUTTON NOT CONNECTED | <p>Situation: A PCA button is required to continue the pump's operation.</p> <p>Action: Connect the PCA button to the pump.</p> <p>NOTE: If the pump is configured to use the START key to administer a PCA dose, this message will not occur.</p> |
| PREVENTIVE MAINTENANCE DUE | <p>Situation: The configured preventive maintenance period has elapsed.</p> <p>Action: Perform the preventive maintenance procedures as described in "Preventive Maintenance," 7-1.</p> <p>NOTE: After its initial occurrence, the PREVENTIVE MAINTENANCE DUE message will appear each time the pump is turned on — until the preventive maintenance is reset.</p> |
| PUMP LEFT IN CONFIG MODE | <p>Situation: The configuration mode time period has elapsed.</p> <p>Action: Press Enter to cancel the alert and restart the configuration mode time period.</p> |
| PUMP LEFT IN PROGRAMMING MODE | <p>Situation: The programming mode time period has elapsed.</p> <p>Action: Press Enter to cancel the alert and restart the programming mode time period.</p> <p>Note: The pump retains all prescription data entered prior to the timeout.</p> |

Table 6-1 Alert Messages and Responses — continued

| Alert Message | Situation/Action |
|-------------------------------|---|
| RELEASE THE <key name> KEY | <p>Situation: A key on the key pad has been pressed continuously for 3 minutes, or the key is stuck.</p> <p>Action:</p> <ol style="list-style-type: none">1. Release the stuck key.2. If this alert occurs and the key is not being pressed intentionally, there may be a mechanical or electronic fault in the key. Do not use the pump. Take the pump out of service and contact your nearest authorized service center. |
| RELEASE PCA BUTTON | <p>Situation: The PCA button has been pressed continuously for 3 minutes.</p> <p>Action:</p> <ol style="list-style-type: none">1. Release the PCA button.2. Advise the patient to press the PCA button briefly when requesting a PCA dose.3. If this alert occurs and the PCA button is not being pressed intentionally, there may be a mechanical or electronic fault in the PCA button. Do not use the pump. Take the pump out of service and contact your nearest authorized service center. |

Table 6-1 Alert Messages and Responses — continued

| Alert Message | Situation/Action |
|-----------------|---|
| REPLACE BATTERY | <p>Situation: The pump does not sound a tone for this alert. The pump is running on AC and the battery power remaining is too low to power the pump. This message is displayed in Run mode on the second line of the screen.</p> <p>Action: Replace the battery as described in “Installing and Changing the Battery,” 3-2.</p> |

Alarms

Alarm messages are described in alphabetical order in this section, with step-by-step procedures for their resolution.

Table 6-2 Alarm Messages and Responses

| Alarm Message | Situation/Action |
|---|--|
| AIR IN TUBING PRESS ENTER ! WARNING ! The air sensor detects and measures the accumulated amounts of air over an amount of fluid delivered. However, the pump may not detect all instances of micro or "champagne" air bubbles. | <p>Situation: The pump has detected air in the tubing set. The infusion is stopped.</p> <p>Action:</p> <ol style="list-style-type: none">1. Press Enter. The pump will display the START TO PRIME, ENTER TO PROCEED prompt. <p>! WARNING !</p> <p>The tubing set MUST NOT be connected to the patient while priming.</p> <ol style="list-style-type: none">2. Disconnect, check, and possibly aspirate the tubing set. See "Preparing, Loading, and Changing the Tubing Set and Fluid Bag," 3-13 and "Prime the Tubing Set," 5-16. Press START to begin priming. <p>OR</p> <ol style="list-style-type: none">3. Press Enter to continue if air does not need to be purged. |

Table 6-2 Alarm Messages and Responses — continued

| Alarm Message | Situation/Action |
|------------------------|--|
| BATTERY IS DEPLETED | <p>Situation: The pump is running on battery power and the battery power remaining is too low to continue.</p> <p>Action:</p> <ol style="list-style-type: none">1. Replace the dead battery as soon as possible as described in “Installing and Changing the Battery,” 3-2.2. If necessary, connect the pump to the AC adapter (see “Connecting the AC Adapter,” 3-5). |
| CHECK TUBING PLACEMENT | <p>Situation: The tubing set is either improperly loaded or damaged.</p> <p>Action:</p> <ol style="list-style-type: none">1. Ensure that the set is not damaged and is properly loaded. For information on loading the tubing set, refer to “Preparing, Loading, and Changing the Tubing Set and Fluid Bag,” 3-13. <p>NOTE: If the tubing door is opened and closed, the upstream occlusion test will run when START is pressed. See “Upstream Occlusion Testing,” 5-18.</p> <ol style="list-style-type: none">2. If the alarm condition persists, a sensor failure may exist. Do not use the pump. Take the pump out of service and contact your nearest authorized service center. |

Table 6-2 Alarm Messages and Responses — continued

| Alarm Message | Situation/Action |
|--------------------------|---|
| CODE INCORRECT | <p>Situation: Three invalid security codes have been entered.</p> <p>Action:</p> <ol style="list-style-type: none">1. If the pump is configured as KEY+CODE, unlock the cover, lock it again, and enter the security code.2. If it is configured as CODE ONLY, turn off the pump and turn it on again. |
| COMMUNICATION TIMEOUT | <p>Situation: The configuration mode transfer was incomplete or was interrupted.</p> <p>Action: Press Clear/Silence to cancel the alarm and return to the START TO PROCEED CLEAR TO CANCEL display.</p> |
| COVER IS UNLOCKED | <p>Situation: The cover is unlocked while the pump is active and the pump is configured for KEY+CODE or KEY ONLY.</p> <p>Action: Lock the cover, and press the START key to resume the infusion.</p> |

Table 6-2 Alarm Messages and Responses — continued

| Alarm Message | Situation/Action |
|--|---|
| <p>DOWNSTREAM OCCLUSION</p> <p>Note: Make sure the tubing set is not kinked or blocked downstream of the pump.</p> | <p>Situation: The pump has detected an occlusion or blockage between the pumping mechanism and the patient that is preventing fluid flow. The infusion stops.</p> <p>Action:</p> <ol style="list-style-type: none">1. Check the tubing set for closed clamps and kinks.2. If no closed clamps or kinks are found, engage the distal slide clamp before opening the tubing door to check for tubing obstructions.3. Check the injection site.4. When the pump detects that the occlusion has been cleared, it will resume operation automatically, or press START to resume the infusion after the occlusion has been cleared. <p>NOTE: If the tubing door is opened and closed, the upstream occlusion test will run when START is pressed. See “Upstream Occlusion Testing,” 5-18.</p> |

Table 6-2 Alarm Messages and Responses — continued

| Alarm Message | Situation/Action |
|-----------------------|---|
| EMPTY | <p>Situation: The fluid bag is empty.</p> <p>Action:</p> <ol style="list-style-type: none">1. Replace the fluid bag with a filled fluid bag.2. Reprogram the fluid volume and prime as described in “Set the Fluid Volume in the Reservoir,” 5-15 and “Prime the Tubing Set,” 5-16. |
| RELEASE PCA BUTTON | <p>Situation: The PCA button has been pressed continuously for 6 minutes.</p> <p>Action:</p> <ol style="list-style-type: none">1. Release the PCA button.2. Advise the patient to press the PCA button briefly when requesting a PCA dose. <p>NOTE: If this alarm occurs and the PCA button is not being pressed intentionally, the PCA button may have a mechanical or electronic fault. Do not use the pump. Take the pump out of service and contact your nearest authorized service center.</p> |

Table 6-2 Alarm Messages and Responses — continued

| Alarm Message | Situation/Action |
|--|--|
| <p>SET NOT PRIMED PRESS ENTER</p> <p>Note: If no air is visibly present in the shorter end of the tubing set, reload the tubing set, ensuring the shorter end is not stretched.</p> | <p>Situation: Air is detected in the tubing during the upstream occlusion test.</p> <p>Action:</p> <ol style="list-style-type: none">1. Press Enter. The pump will display the START TO PRIME, ENTER TO PROCEED prompt. <p>! WARNING !</p> <p>The tubing set MUST NOT be connected to the patient while priming.</p> <ol style="list-style-type: none">2. Press START: If the pump is configured as KEY+CODE or CODE ONLY, enter the security code at the 000 ENTER CODE prompt, and press Enter. If the pump is configured as KEY ONLY, unlock and lock the fluid bag cover at the UNLOCK THE COVER and LOCK THE COVER prompts. Priming begins (see “Prime the Tubing Set,” 5-16).3. After the tubing set is primed, press Enter for the PUMP READY, START OR CLEAR prompt.4. Press START to run the upstream occlusion test again and begin infusing. |

Table 6-2 Alarm Messages and Responses — continued

| Alarm Message | Situation/Action |
|------------------------------------|--|
| SOFTWARE VERSION ERROR-RECONFIG | <p>Situation: The software version does not match the pump configuration.</p> <p>Action:</p> <ol style="list-style-type: none"><li data-bbox="416 400 1083 431">1. Turn off the pump, and then turn it on again.<li data-bbox="416 456 1498 533">2. Reconfigure the pump as described in the <i>Ipump Pain Management System Device Configuration Manual</i>. |

Table 6-2 Alarm Messages and Responses — continued

| Alarm Message | Situation/Action |
|---------------------------------|--|
| SYSTEM ERROR XX SERVICE PUMP | <p>Situation: A system error has been detected by the microprocessor and the pump is inoperable. The two-character code (XX) refers to a specific malfunction as listed in the <i>Ipump Pain Management System Service Manual</i>.</p> <p>Action:</p> <ol style="list-style-type: none">1. Record the system error code.2. Turn off the pump, and then restart the pump.3. If no system error code is displayed, continue to use the pump.4. If the same code or a new code is displayed after the restart, do not use the pump. Take the pump out of service and contact your nearest authorized service center. |

Table 6-2 Alarm Messages and Responses — continued

| Alarm Message | Situation/Action |
|--|--|
| <p>UPSTREAM OCCLUSION</p> <p>Note: Make sure the tubing set is not kinked or blocked upstream of the pump.</p> | <p>Situation: The pump has detected an occlusion or blockage between the fluid bag and the pumping mechanism that is preventing fluid flow. During an infusion, the infusion stops.</p> <p>Action:</p> <ol style="list-style-type: none">1. Open the cover and check the tubing and bag for closed clamps and kinks.2. If no closed clamps or kinks are found, engage the distal slide clamp before opening the tubing door to check for tubing obstructions.3. After clearing the occlusion, press START to resume the infusion. <p>NOTE: If the tubing door has been opened and closed, or if this alarm condition occurred during the upstream occlusion test, the upstream occlusion test will run before the infusion begins. See “Upstream Occlusion Testing,” 5-18.</p> |

Chapter 7. Preventive Maintenance

Baxter recommends performing preventive maintenance on an annual basis and cleaning after every use. If the device cannot be cleaned using the methods described herein or components are missing or damaged, discontinue use and notify the appropriate authorized service personnel.

Authorized Service Centers

In North America, call the Medication Delivery Global Technical Services Center at 1-800-THE-PUMP.

Outside North America, visit www.baxter.com/baxter_worldwide.html or call your Baxter customer service representative to locate the nearest service center.

Cleaning the Pump

Clean the pump and PCA button with a soft cloth, sparingly dampened with any of the cleaners listed in Table 7-1 on page 7-2.

Note: Some of the listed cleaners may not be available at your location. Use any of the available listed cleaners.

Cleaning the Carrying Case

To clean the Carrying Case refer to the tag located inside the case: Machine Wash, Cold Gentle Cycle, Non-Chlorine Bleach, Drip Dry.

Table 7-1 Recommended Cleaners

| Recommended Cleaner | Manufacturer | Cleaner | Disinfectant |
|------------------------------------|----------------------------------|----------------|---------------------|
| Soapy water | n/a | XXX | |
| A solution of 10% bleach and water | n/a | XXX | XXX |
| LpH | STERIS Corporation | XXX | XXX |
| Septisol | STERIS Corporation | XXX | XXX |
| Super-Edisonite | Colgate-Palmolive Co. | XXX | |
| TOR or Hi-TOR Plus | Huntington Professional Products | XXX | XXX |

As you clean the pump, be careful that you:

- Do not spray the cleaner directly onto the pump.
- Do not use hard instruments for cleaning.
- Follow manufacturer's dilution instructions for concentrated cleaners.

Always clean/disinfect the pump and PCA button after each use as follows:

| Type of use | Action |
|---|---|
| If the device has been in an isolation area | Select those agents from the list that both clean and disinfect. |
| If the device has been used on a patient | Clean/disinfect with an agent from the recommended list of cleaners before use on another patient. |
| If spills occur or the device is dirty | Clean as quickly as possible to minimize any potential difficulties with the solutions pooling and drying on the mechanism. If fluid enters the tubing channel, contact your local Baxter Service Center (see “Authorized Service Centers,” 7-1). |

! WARNING !

Liquids must not be allowed to enter the inside of the pump through the battery compartment, or through the power, printer, or PCA ports. Liquid ingress into the pump may cause the pump to fail or operate in an unintended manner during the current or future patient use.

CAUTION

The Ipump Pain Management System is not waterproof and should not be immersed in water. Avoid getting liquids inside the pump. Air sensor functioning could be compromised or permanent damage may result. Do not use alcohol for cleaning.

CAUTION

Do not clean, disinfect, or sterilize any part of the device by autoclaving or with ethylene oxide gas. Doing so may damage the device and void the warranty. Only external parts of the device should be disinfected.

Preventive Maintenance Checklist

The following is a schedule of basic maintenance tasks that should be performed on the device.

| Cleaning and Inspection | |
|--|--|
| Perform as required, but recommended after every use. NOTE: Clean using one of the recommended cleaners listed in Table 7-1 on page 7-2. | |
| Check | Action |
| Housing | Clean housing and front panel as recommended in “Cleaning the Pump,” 7-1. Check for cracks or large dents. |
| Tubing door | Verify that the tubing door opens freely and that the latching mechanism operates properly when the door is closed. |
| Labels | Clean as recommended in the cleaning instructions. Check for scratches, cuts, or obliterated words. |
| AC adapter | Verify that the optional AC adapter is undamaged over the entire length of the cord and the molded plugs. |
| Cover | Clean as recommended in “Cleaning the Pump,” 7-1. Ensure that the cover is intact, fits properly when closed and locked, and has no obvious cracks or fractures. |
| Pole clamp | Operates freely throughout range of motion. Check that the pump stays on IV pole. |
| PCA button and cord | Clean as recommended in “Cleaning the Pump,” 7-1. Ensure that the cord is intact and has no cuts or missing insulation, and that the connector and the PCA button are securely attached to the cord. |

Functional Testing

Perform as required, but recommended every 6 months.

| Check | Action |
|---------------|---|
| Entire device | Schedule functional test by qualified biomedical personnel or authorized service personnel as specified in the <i>Ipump Pain Management System Service Manual</i> . |

Transporting and Storing the Pump

When unpacked, store the pump without the battery in a clean and dry environment to safeguard against prolonged exposure to dust and moisture. This storage area should meet the following environmental guidelines:

- Temperature range: -20°C to 60°C (-4°F to 140°F)
- Relative humidity: 10% to 95% (non-condensing)

If conditions fall outside these limits, Baxter recommends that the device be repackaged in the original shipping materials.

Note: When storing the pump, remove the 9-volt battery from the pump. Always store the pump with the tubing door closed.

Repair and Troubleshooting

The pump must be serviced only by authorized personnel who have completed the manufacturer's technical training program. Service documentation, including circuit diagrams, is available to approved service organizations upon request. Alternatively, the pump should be returned to Baxter for service.

While under Baxter's warranty, Service Agreement (optional), or lease agreement, the pump housing must not be opened by unauthorized personnel. Use an authorized Baxter service provider for service and repair. For service and repair information for this product, contact your local Baxter Service Center.

In the event that your pump needs to be returned for service, obtain a Return Authorization by contacting your local service center (see "Authorized Service Centers," 7-1). Shipping costs for all pumps returned to Baxter shall be paid for by the customer. The pump must be packed in its original container or in another Baxter approved container that will provide adequate protection during shipment. To ensure prompt return, a Baxter authorized service representative must be notified before shipping any pump for repair. When calling for service, please be prepared to provide code number and serial number of the pump. A brief written description of the problem should be attached to the pump when it is returned for service.

Baxter will not be responsible for unauthorized returns or for units damaged in shipment due to improper packaging.

Chapter 8. Accessories, Disposables, and Recommended Sets

Note: All items may not be available in your region. Contact your Baxter customer service representative for assistance.

Table 8-1 Accessories, Disposables, and Recommended Sets

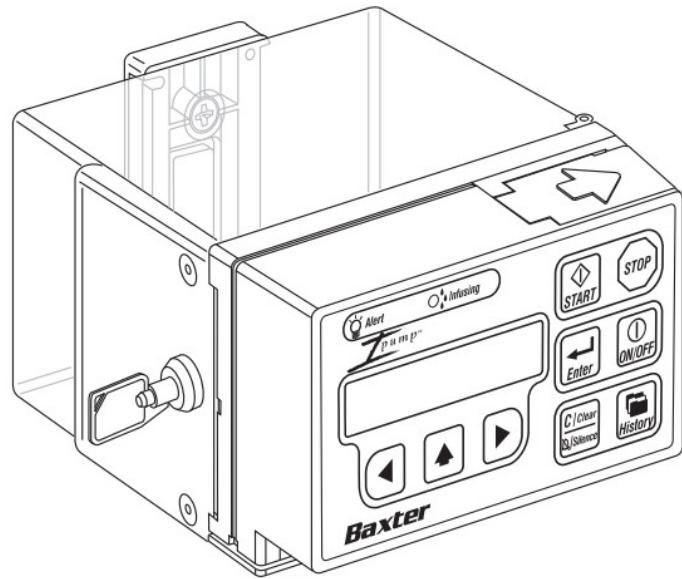
| Component | Description | Product Number |
|------------------|--|--|
| Bags | Empty 100 mL luer-lock bag | 2L3256 2L3256K |
| | Empty 250 mL luer-lock bag | 2L3257 2L3257K |
| | Empty Non-PVC IntraVia Spike Containers with PVC Ports 50 mL 150 mL 250 mL 500 mL | 2B8019 2B8011 2B8012 2B8013 |
| | Viaflex Bags in the following container sizes 50 mL 100 mL 150 mL 250 mL 500 mL | For specific product numbers, contact your local Baxter representative to determine the desired solution and container size. |
| | | |

Table 8-1 Accessories, Disposables, and Recommended Sets — continued

| Component | Description | Product Number |
|--|--|-----------------------|
| Administration Sets | 2.6 m (104") Epidural Luer Lock Set | 2L3504 |
| NOTE: Sets' maximum pressure is 2326 mmHg (45 psi). | 0.2 m (8") Anti-Reflux Y-Site Extension Set | 2L3506 |
| | 1.8 m (72") Luer Lock Set * See WARNING at left. | 2L3510 (US only) |
| NOTE: All pump sets have integral anti-siphon valves to minimize the potential for free flow. | 2.5 m (101") Luer Lock Set * See WARNING at left. | 2L3511 (US only) |
| ! WARNING ! Do not use (2L3510 or 2L3511) at flow rates below 0.5 mL/hr. | 2.7 m (107") Epidural Spike Set | 2L3512 |
| | 2.8 m (110") Air Eliminating Spike Set | 2L3513 |
| | 2.7 m (106") Air Eliminating Luer Lock Set | 2L3520 |
| | 3.1 m (122") Epidural Spike Set for 500 mL Bag Cover | 2L3522 |
| | 3.1 m (123") Air Eliminating Spike Set for 500 mL Bag Cover | 2L3523 |
| | 2.9 m (113") Air Eliminating Spike Set with Integral Y-Site | 2L3525 |
| | 2.8 m (110") Air Eliminating Luer Lock Set with Integral Y-Site | 2L3526 |
| | 3.2 m (126") Air Eliminating Spike Set with Integral Y-Site for 500 mL Bag Cover | 2L3527 |
| | 0.9 m (36") Air Eliminating Extension Set | 2N3347 |

Table 8-1 Accessories, Disposables, and Recommended Sets — continued

| Component | Description | Product Number |
|-----------------------|---|-----------------------|
| Printer Accessories | Printer Adapter | 2L3400 |
| | Printer Adapter Cable | 2L3402 |
| Miscellaneous Options | Patient Controlled Analgesia Button | B069140003RP |
| | Locking Pole Mount Clamp (optional) | 2L3211 |
| | Non-locking Pole Mount Clamp (optional) | 2L3212 |
| | Pump Carrying Case (cloth) | 2L3219 |
| | Configuration Transfer Cable | 2L3112 |
| Locking Bag Covers | 100 mL Cover | 2L3218 |
| | 250 mL Cover | 2L3220 |
| | 250E mL Cover | 2L3217 |
| | 500 mL Cover | 2L3221 |
| AC Adapters | AC Adapter (100-120V) — US | 2L3210 |
| | AC Adapter (220-240V) — UK/Europe | 2L3205K |



Chapter 9. Technical Specifications

| Component | Description |
|--|--|
| AC Power Requirements (when used with optional AC adapter) | With 2L3210 adapter: 100 to 120 VAC 60 Hz With 2L3205K adapter: 220 to 240 VAC 50 Hz, 700mA |
| DC Power Requirements | 9V alkaline battery Typical operating time when operating at an intermediate rate of 1 mL/hr is approximately 140 hours. Typical operating time when operating at a rate of 10 mL/hr is approximately 76 hours. |
| Leakage Current | Less than 0.3 mA earth leakage (tested per UL 2601-1) |
| AC Adapter Cord (100-120V) — US | Approximately 1.8 m (5.9 feet) long |
| AC Adapter Cord (220-240V) — UK/Europe | Approximately 2.0 m (6.5 feet) long |
| Range of Programmable Flow Rates | 0.1 to 90.0 mL/hr in 0.1 mL/hr increments |
| Maximum Infusion Under Single Fault Conditions | 0.50 mL |
| Flow Rates | Basal Rate: 0.1 to 19.9 mL/hr Continuous Rate: 0.1 to 90.0 mL/hr PCA Dose, Bolus, and Priming Rate: 90.0 mL/hr |

| Component | Description |
|---|---|
| Flow Rate Accuracy | ± 8% at 22°C to 23°C (71.6°F to 73.4°F) nominal; ±10% at the temperature extremes of 10°C (50°F) and 40°C (104°F). See "Environmental Operating Limits," 9-4. |
| Time to Detect Downstream Occlusions | Occlusion alarm delay at 0.1 mL/hr is 2.5 hours (maximum) Occlusion alarm delay at 5 mL/hr is 5.5 minutes (maximum) |
| Bolus Volume Released after Downstream Occlusions are Corrected | Bolus volume after occlusion is 0.5 mL (maximum) |
| Air-in-Line | Air-in-line alarm configured for HIGH sensitivity senses approximately 0.1 mL of air Air-in-line alarm configured for LOW sensitivity senses approximately 0.5 mL of air |
| Maximum Infusion Pressure Generated | The maximum infusion pressure generated prior to alarm activation is 2109 mmHg (41 psi) |
| Downstream Occlusion Alarm Pressure | The downstream occlusion alarm pressure threshold is 1138 ± 517 mmHg (22 ± 10 psi) |
| Operational Features | PCA Dose Volume Selections: 0.0 to 9.9 mL (in 0.1 mL increments) Bolus Volume Selections: 0.0 to 49.9 mL (in 0.1 mL increments) Bag Volume Selections: 1 to 1999 mL Delay Time Selections: 1 to 240 minutes History/Prescription Recall |

| Component | Description |
|----------------------|--|
| Concentration Ranges | When units of mg are selected, the below values are limited to the same volumes as for prescriptions entered in mL. 0.1 mg/mL to 99.9 mg/mL in 0.1 mg/mL increments 1 µg/mL to 999 µg/mL in 1 µg/mL increments |
| Security Features | Locking cover 3-digit programmable security code Latched tubing door |
| Indicators | Alphanumeric description via LCD display Red Alert light Green Infusing light Audible tones: Minimum audible alarm sound level: 50 dBA |
| Battery | 9-volt alkaline |
| Drive Mechanism | DC Motor, microprocessor-controlled, precision linear peristaltic pumping mechanism |
| Printer Port | 1200 Baud, 8 data bits, no parity and 1 stop bit |
| Housing | Shock- and vibration-resistant Acrylonitrile Butadiene Styrene (ABS) |
| Size | 12.4 cm x 8.6 cm x 4.6 cm (4.9" x 3.4" x 1.8") without cover |

| Component | Description |
|--|---|
| Weight | 495 grams (17.5 ounces) with 250E mL bag cover and without a battery |
| Environmental Operating Limits | <p>Temperature: 10°C to 40°C (50°F to 104°F) Humidity: 30% to 75% relative humidity, non-condensing Barometric Pressure: 700 to 1060 hPa (0.6908 to 1.046 atm)</p> <p>! WARNING !</p> <p>While the pump can operate in temperatures from 10°C to 40°C (50°F to 104°F), if used in temperatures below 15°C (59°F) or if cold solutions are used, air sensor functionality may be compromised. For maximum safety, move the pump to an environment above 15°C (59°F) and allow cold solutions to warm to appropriate operating temperatures before use.</p> |
| Environmental Storage and Transport Limits (unpackaged) | <p>Temperature: -20°C to 60°C (-4°F to 140°F) Humidity: 10% to 95% relative humidity (non-condensing, unpackaged) Barometric Pressure: 500 to 1060 hPa (0.4935 to 1.046 atm)</p> |
| Options and Accessories | See “Accessories, Disposables, and Recommended Sets,” 8-1. |

Recommended Practices

Connections of this pump to the same patient line with other infusion systems or accessories may alter the performance of the pump. Consult the manufacturer's instructions for use of the systems or accessories before proceeding. Outside the U.S., read document VDE0753-5 when performing parallel infusions.

To ensure that pump performance is maintained, authorized service personnel should perform preventive maintenance as described in Chapter 7, "Preventive Maintenance." Service personnel should refer to the *Ipump Pain Management System Service Manual* for information on procedures.

Flow Rate Accuracy of the System

The Ipump Pain Management System, using the appropriate Baxter administration sets as identified in Chapter 8, maintains flow rate accuracy with delivery errors not exceeding $\pm 8\%$ at 22°C to 23°C (71.6°F to 73.4°F) nominal and $\pm 10\%$ at the temperature extremes of 10°C (50°F) and 40°C (104°F).

Note that flow fluctuations can be caused by unusual conditions or combinations of conditions that may involve, but are not limited to, the following: fluid density, positive and negative pressure, and the environment. Flow fluctuations are most likely to occur when the conditions mentioned above are exacerbated or when the device is operated in conditions outside of its normal limits. See "Environmental Operating Limits," 9-4.

Startup Graph Description

The Startup Graph was developed in accordance with IEC 60601-2-24. The Startup data shown in the graph illustrates the startup performance of the Ipump Pain Management System during the first 24 hours of operation with a sampling period of 15 minutes.

! WARNING !

During upstream occlusion testing, the pump may withdraw up to 0.03 mL of fluid and subsequently deliver up to 0.09 mL of fluid at the end of the test period. If these volumes are clinically significant for the patient, please take the appropriate measures. See “Upstream Occlusion Testing” for more details.

A Startup Graph of flow versus time (Figure 9-1) illustrates initial stability with time. Even with proper components and set up, the flow of any manufacturer's pump may be erratic during the initial startup period. Therefore, we have included the startup, or stabilization data. It should be noted that as the time interval over which accuracy is measured is lengthened, all pumps show considerable improvement in flow accuracy.

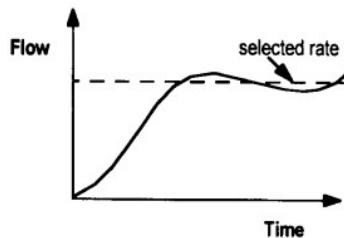


Figure 9-1 Startup Graph Example

How Trumpet Graphs are Interpreted

The Trumpet Curve graph (Figure 9-2) provides a graphical view of the maximum deviation in flow rate from the programmed delivery rate for specific segments of delivery time. The horizontal axis does **not** represent elapsed delivery time, but rather acts as a graphical reference for selecting specific observation time intervals. The widest area of the trumpet curve (greatest deviation) reflects the smallest sampling intervals or observation windows. As the sizes of the sampling intervals increase (in minutes), the deviations in flow from the programmed delivery rate are reduced as the deviations are spread out over the longer periods of time. This results in the narrowing of the trumpet curve giving a more realistic representation of the device's average flow rate accuracy over longer intervals of time.

For example, if you were to look at the maximum and minimum percentage error points corresponding to the 60-minute interval point on the Observation Interval axis, you would be looking at the average flow variance for any 60-minute period throughout the infusion.

How Trumpet Graphs are Created

The Trumpet Curve graphs were developed in accordance with data collection and manipulation methods defined in IEC 60601-2-24.

The Trumpet Curve graphs were created in the following manner.

- Fluid from the device is collected at the set flow rates over 25 hours.
- Every 15 minutes, the cumulative weight of the fluid is recorded.
- The data from the collection period are divided into observation or time windows and the flow rate accuracy is determined for each window.
- The maximum and minimum deviations from the set flow rate for various window sizes (15, 60, 150, 330, 570, and 930 minutes) are plotted on a graph.
- These plotted points are connected to form the trumpet-shaped lines.

How Trumpet Graphs Can be Used

Trumpet Curve graphs can be important sources of information for the medical professional who must decide whether a certain infusion pump can be used with a particular medication. For example, when delivering a medication with a short half-life, very small deviations in flow over the course of an infusion would be desirable to ensure that the deviations in plasma level also remained small. The device's ability to deliver very closely to the programmed rate would ensure that the medication's efficacy was being maintained. In this example, the medical professional would be wise to select a device whose trumpet curve indicated a small or narrow range of deviations in flow rate.

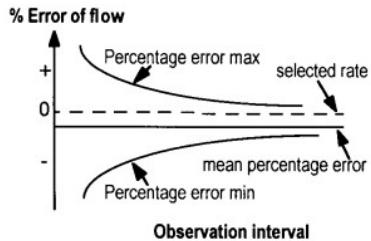
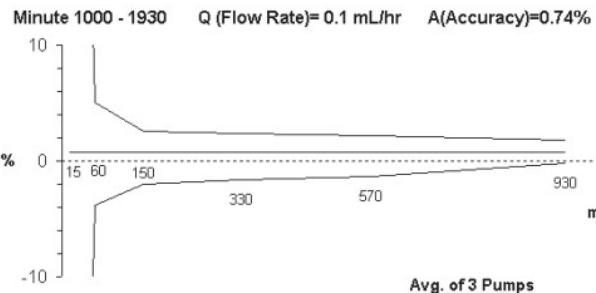
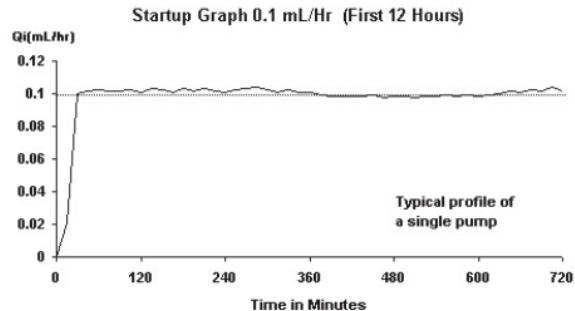
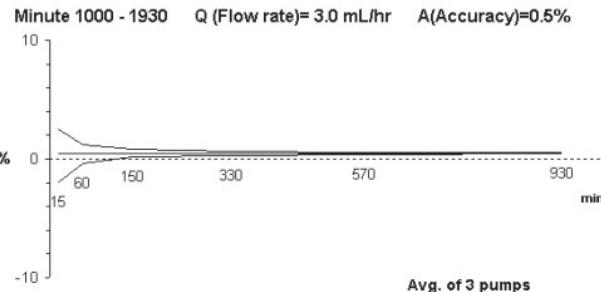
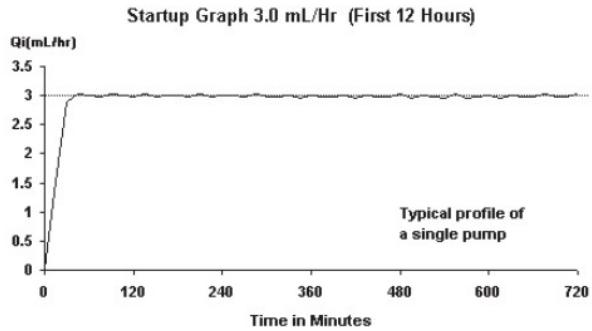


Figure 9-2 Trumpet Graph Example

Startup and Trumpet Graphs at 0.1 mL/hr



Startup and Trumpet Graphs at 3.0 mL/hr



List of Materials

Note: No natural latex was used in the manufacture of this pump.

- Acrylonitrile Butadiene Styrene (ABS)
- Polycarbonate (PC)
- Acetal + Polytetrafluoroethylene (PTFE)
- Polyester
- Nylon
- Synthetic rubber
- Brass (nickel-plated)
- Zinc (die-cast)
- Aluminum
- Stainless steel
- Iron (chrome-plated)
- Polyvinyl-Chloride (PVC)
- Polyphenyl Sulphone

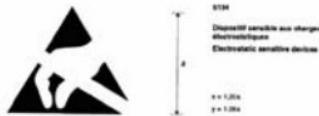
Chapter 10. Electromagnetic Compatibility Statement

This statement and the information provided in the following tables are required by IEC 60601-1-2, second edition. The tables can be used to identify the EMC standards Ipump Pain Management System (hereinafter referred to as the “pump”) was subjected to, the minimum test level identified in the standard, the level that the pump meets, and general guidance on the EMC environment. The pump is intended for use in the electromagnetic environment specified in the following tables. As with most microprocessor-based electronic products, the pump creates RF (radio frequency) energy as a side effect of its internal functions.

Precautions should be taken to avoid exposing the pump to powerful sources of electromagnetic radiation such as MRI (magnetic resonance imaging) and ESU (electro-surgical equipment).

Note: Portable and mobile communications equipment such as cell phones can affect medical electrical equipment such as the pump.

The connector testing exemption allowed by IEC 60601-1-2: 2001, Ed. 2.0 is being used for the pump PRINTER/COMM connector. This exemption from testing allows for performance that does not meet the ESD (electrostatic discharge) test levels required by IEC 60601-1-2: 2001, Ed. 2.0. The following symbol, located adjacent to the PRINTER/COMM connector is used to identify the connector as being sensitive to ESD:



Note: Table 10-2, *Guidance and Manufacturer's Declaration - Electromagnetic Immunity*, contains additional information that is required by IEC 60601-1-2: 2001, Ed. 2.0 in order to use the connector testing exemption.

! WARNING !

The use of accessories and cables, other than those specified in the operator's manual, may result in increased emissions or decreased immunity of the pump.

CAUTION

The pump should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary, the pump should be observed to verify normal operation in the configuration in which it will be used.

Table 10-1 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

| The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should assure that it is used in such an environment. | | |
|--|-------------------|--|
| Emission Test | Compliance | Electromagnetic Environment - Guidance |
| RF emissions CISPR 11 | Group 1 | The pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | The pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Not applicable | |

Table 10-2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

| The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should assure that it is used in such an environment. | | | |
|--|--|--|---|
| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact ± 8 kV air | ± 8 kV contact ± 8 kV air (1) ± 15 kV air (2) ± 4 kV air (1)(2) | Floors should be wood, concrete, or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%. Functions normally except at PRINTER/COMM connector pins. Pump may stop infusing and alarm at levels above ± 8 kV air. Avoid touching the PRINTER/COMM connector pins directly. |

Table 10-2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity — continued

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|--|--|---|---|
| Electrical fast transient burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines Not Applicable (3) | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV differential mode ± 2 kV common mode | ± 1 kV differential mode ± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |

Table 10-2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity — continued

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|--|--|--|--|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec. | <5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec. | Mains power quality should be that of a typical commercial or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or a battery. User should always have battery installed per operator's manual. (4) |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m 400 A/m (2) | Power frequency magnetic characteristic of a typical location in a typical commercial or hospital environment. Pump may stop infusing and alarm at levels above 3A/m. |

Table 10-2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity — continued

| Notes for Table 10-2 | |
|-----------------------------|---|
| Note 1 | <p>! WARNING !</p> <p>The pins of the PRINTER/COMM connector should not be touched. The PRINTER/COMM connector should not have objects inserted into it other than the mating connector. ESD precautionary procedures should be used when inserting the mating connector into the connector.</p> <p>It is recommended that all staff involved in the use or servicing of this device receive training in the ESD precautionary procedures. The ESD precautionary procedures should include:</p> <ul style="list-style-type: none">• an introduction to the physics of electrostatic charge;• the voltage levels that can occur in normal practice;• the damage that can be done to electronic components by electrostatic discharge;• an explanation of methods to prevent build up of electrostatic charge;• an explanation on why to discharge one's body to earth or a large metal object;• an explanation on bonding oneself by means of a wrist strap to earth prior to servicing. |
| Note 2 | The pump was tested to the EMC requirements of IEC 60601-2-24: 1998. IEC 60601-2-24, the particular standard for infusion pumps, requires higher test levels. |
| Note 3 | Input/output lines are exempt because they are less than 3.0 meters long. |
| Note 4 | The pump automatically transfers to battery operation if there is a loss of mains power. |

**Table 10-3 Guidance and Manufacturer's Declaration –
Electromagnetic Immunity- for Life-Supporting Equipment and Systems**

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic environment - guidance |
|-------------------------------|--|--------------------------|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz TO 80 MHz outside ISM bands ^a 10 Vrms 150 kHz to 80 MHz in ISM bands ^b | 3 Vrms 3 Vrms (3) | <p>Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d=1.2\sqrt{P}$ $d=4\sqrt{P}$ |

**Table 10-3 Guidance and Manufacturer's Declaration –
Electromagnetic Immunity- for Life-Supporting Equipment and Systems — continued**

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic environment - guidance |
|------------------------------|-----------------------------|-----------------------|---|
| Radiated RF IEC 61000-4-3 | 10 V/m 80 MHz to 2.5 GHz | 3 V/m (3) 10V/m(3) | <p>d=4\sqrt{P} 80 MHz to 800 MHz d=7.7\sqrt{P} 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^c, should be less than the compliance level in each frequency range.^d</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  <p>Pump may stop infusing and alarm at levels above 3V/m.</p> |

**Table 10-3 Guidance and Manufacturer's Declaration –
Electromagnetic Immunity- for Life-Supporting Equipment and Systems — continued**

| Notes for Table 10-3 | |
|-----------------------------|---|
| Note 1 | At 80 MHz and 800 MHz, the higher frequency range applies. |
| Note 2 | These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. |
| Note 3 | The pump was tested to the EMC requirements of IEC 60601-2-24: 1998. IEC 60601-2-24, the particular standard for infusion pumps, requires higher test levels. |
| (a) | The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. |

**Table 10-3 Guidance and Manufacturer's Declaration –
Electromagnetic Immunity- for Life-Supporting Equipment and Systems — continued**

| | |
|-----|--|
| (b) | The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges. |
| (c) | Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the pump. |
| (d) | Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. |

Table 10-4 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Pump – for Life-Supporting Equipment and Systems

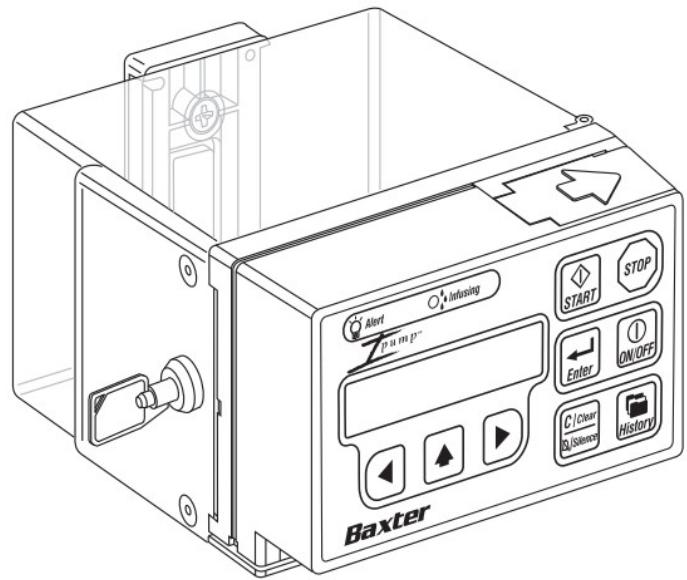
The pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump as recommended below, according to the maximum output power of the communications equipment.

| Rated Maximum Output Power of Transmitter (W) | Separation Distance According to Frequency of Transmitter (m) | | | |
|---|---|---|------------------------------------|---------------------------------------|
| | 150 kHz to 80 MHz outside ISM bands $d=1.2\sqrt{P}$ | 150 kHz to 80 MHz in ISM bands $d=4\sqrt{P}$ | 80 MHz to 800 MHz $d=4\sqrt{P}$ | 800 MHz to 2.5 GHz $d=7.7\sqrt{P}$ |
| 0.01 | 0.12 | 0.40 | 0.40 | 0.77 |
| 0.1 | 0.38 | 1.3 | 1.3 | 2.4 |
| 1 | 1.2 | 4.0 | 4.0 | 7.7 |
| 10 | 3.8 | 13 | 13 | 24 |
| 100 | 12 | 40 | 40 | 77 |

Notes for Table 10-4

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

| | |
|--------|--|
| Note 1 | At 80 MHz and 800 MHz, the separation distance of the higher frequency range applies. |
| Note 2 | The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. |
| Note 3 | An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. |
| Note 4 | These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. |



Glossary

| Term | Definition |
|---------------|--|
| AC | Alternating Current |
| alarm | An event, marked by a flashing ALERT LED, repeating alert tone, and specific display message that signals a condition requiring a response by the operator and stops any motor movement (<i>see also: system alarm</i>). |
| alarm log | A record of pump system alarms by date and time, maintained in non-volatile memory even though the power is turned off. |
| alert | An event, marked by a flashing ALERT LED, repeating alert tone, and specific message (unless otherwise indicated), that provides important status information or signals a condition requiring a response by the operator. |
| attempt | The patient action (either the depression of the PCA button or START key) intended to initiate a PCA dose. |
| basal rate | The programmed continuous infusion rate when the pump is operating in Basal+PCA mode. |
| bolus | The quantity of drug that, if programmed, is either delivered automatically at the start of therapy, or initiated by the clinician during the course of therapy. |
| concentration | The programmed amount of drug in milligrams or micrograms per milliliter of fluid. |

| Term | Definition |
|------------------------|---|
| configuration group | A collection of functionally related configuration settings contained in the configuration record. |
| configuration record | A data block, maintained in nonvolatile memory, that consists of settings that enable, disable, control, or limit specific pump features and functions. The configuration record can be modified by the operator in a special mode accessible by a security code. |
| continuous rate | The programmed continuous infusion rate when the pump is operating in CONT mode. |
| critical data | Data that are critical to the operation of the pump, including prescription, configuration, and historical data. |
| delay | The programmed time interval that must elapse between the start of therapy and the initial PCA dose or between the start (of delivery) of one PCA dose and the start of the next PCA dose. |
| Doses per Hour Limit | The programmed maximum number of PCA doses that may be delivered in a one-hour period. |
| event log | A record of significant operator actions that occur during a single therapy, and related data; each action entry is date- and time-stamped, and the event log is maintained in non-volatile memory. |
| fluid volume | Programmed initial amount of fluid in the infusion bag. |
| Four Hour Limit | The programmed maximum volume of a drug that may be delivered in a four-hour period. |
| Ipump Device or System | Ipump Pain Management System |

| Term | Definition |
|---------------------|--|
| initial bolus | (Sometimes referred to as a “Loading Dose”.) The bolus dose delivered automatically at the start of therapy. |
| INITIAL Rx | The purpose of this feature is to support standardized therapy. The word INITIAL represents that the prescription saved in the pump is the first (or initial) prescription set for the previous patient. |
| INJ/ATT shift total | The total number of injections and attempts since the start of therapy or since the operator last cleared the total for the current shift. |
| LCD | Liquid Crystal Display |
| LED | Light Emitting Diode |
| mg | Milligram |
| mL | Milliliter |
| One Hour Limit | The programmed maximum volume of drug that may be delivered in a one-hour period. |
| operator, user | A professional healthcare person (clinician or biomedical engineer). |
| PCA | Patient Controlled Analgesia |
| PCA dose | The programmed volume of drug to be injected when requested by the patient. |

| Term | Definition |
|-------------------|--|
| Prescription (Rx) | The complete set of program data including infusion mode, units, and, where applicable, concentration, PCA dose size, delay, dose limit, infusion rate and bolus size. |
| shift total | The calculated volume of fluid given since the start of therapy or since the operator last cleared the shift total. |
| system alarm | An event, marked by a flashing ALERT LED, system alarm tone, and error message, generated by the pump in response to an unrecoverable system failure. |
| therapy | A course of treatment using a programmed prescription and initiated by a START key press, during which a patient may receive one or more bolus doses, one or more PCA doses, and/or a continuous infusion. |
| therapy history | A collection of data, maintained in nonvolatile memory, that relates to the most recent or current therapy, consisting of the prescription data, current alarm status, and infusion totals (hourly, by shift, and for the entire therapy). |
| total given | The calculated volume of fluid given since the start of therapy. |
| μg | Microgram |
| volume remaining | The calculated amount of fluid left in the infusion bag. |
| WEEE | Waste Electrical and Electronic Equipment Directive (refer to page 1-8). |

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This manual was printed on paper stock created with 20% de-inked post-consumer waste fiber and a total of 100% recycled fiber.



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Deerfield, IL 60015 USA